Filed Pursuant to Rule 424(b)(4)
Registration No. 333-248447

PROSPECTUS

3,000,000 Shares
Common Stock

Virios Therapeutics, Inc.

This is a firm commitment initial public offering of our common stock. No public market currently exists for our shares. We are offering 3,000,000 shares of our common stock at an initial public offering price of $10.00.

We have been approved to list our common stock on the Nasdaq Capital Market under the symbol "VIRI."

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our common stock is highly speculative and involves a high degree of risk. See "*Risk Factors*" beginning on page 12 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$ 10.00	$30,000,000
Underwriting discounts and commissions[(1)]	$ 0.70	$ 2,100,000
Proceeds to us, before expenses	$ 9.30	$27,900,000

(1) We have agreed to reimburse the underwriter for certain expenses and the underwriter will receive compensation in addition to underwriting discounts and commissions. See the section titled "*Underwriting*" beginning on page 121 of this prospectus.

We have granted the underwriters a 45-day over-allotment option to purchase up to 450,000 additional shares of common stock at the initial public offering price less underwriting discounts and commissions.

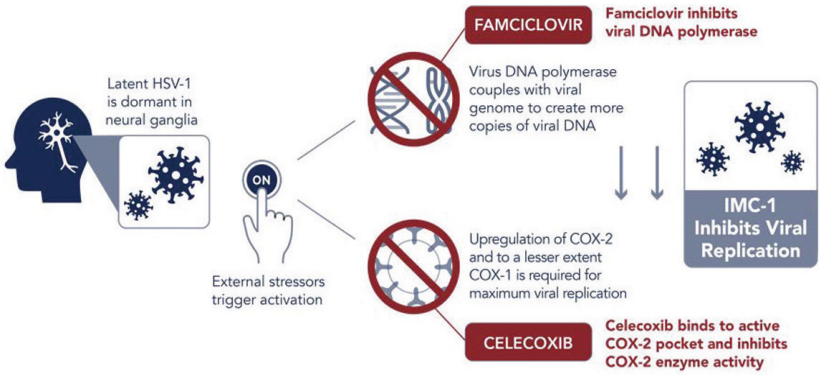
The underwriters expect to deliver our shares to purchasers in the offering on or about December 21, 2020.

ThinkEquity
a division of Fordham Financial Management, Inc.

The date of this prospectus is December 16, 2020

VIRIOS Therapeutics

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



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We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Unless the context otherwise requires, we use the terms "company," "we," "us" and "our" in this prospectus to refer, prior to the Corporate Conversion, to Virios Therapeutics, LLC, and after the Corporate Conversion, to Virios Therapeutics, Inc.

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 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 development candidate ("IMC-1"), is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination antiviral therapy designed to synergistically suppress HSV-1 activation and replication, with the end goal of reducing viral mediated disease burden.

Clinical Observation Leads to Positive Phase 2a Results Portend the Potential of IMC-1 to Treat Fibromyalgia

The potential of IMC-1 in FM is underpinned by statistically significant improvement versus placebo in the primary endpoint of pain reduction in a double-blinded, placebo-controlled, randomized Phase 2a proof-of-concept study in FM patients. In this proof of concept study, IMC-1-treated FM subjects experienced statistically significant clinical effects on both primary endpoint of pain assessment and secondary endpoint measures of pain reduction, reduction in fatigue and improvement in the global health status. 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. 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 three 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.

How does IMC-1 work?

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 and thus inhibits upregulation of the HSV-1 virus. The celecoxib component of IMC-1 inhibits cyclooxegenase-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. We are unaware of any other treatments similar to IMC-1 that inhibit both HSV-1 activation and subsequent HSV-1 replication, with the goal of keeping tissue resident HSV-1 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 combination therapy generated a result in preliminary studies that is greater than the sum of its parts.

Our Novel Mechanism of Action ("MOA")

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.

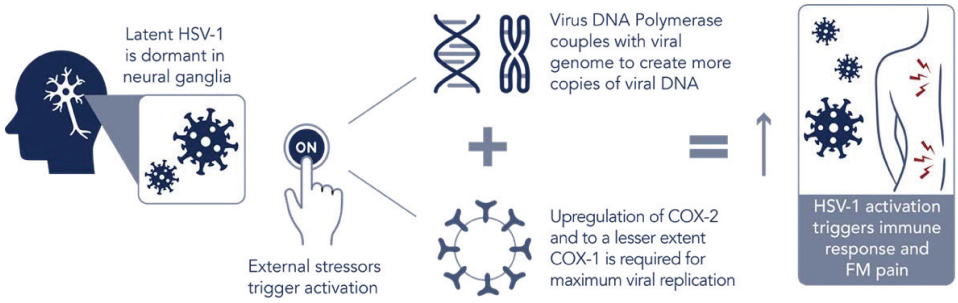
Our novel therapeutic is directed at interrupting the ongoing immune response by suppressing HSV-1, which suppresses the abnormal stress response, thereby alleviating the central pain processing abnormality and other FM symptoms. Studies have shown that neither antivirals nor COX-2/nonsteroidal anti-inflammatory drugs ("NSAIDS") taken alone result in a meaningful clinical benefit. However, when administered in combination, a synergistic response has been observed in preliminary clinical studies. The IMC-1 Phase 2a study generated proof-of-concept evidence of clinically significant pain reduction and symptom alleviation through the coaction of the proprietary, fixed-dose combination of celecoxib and famciclovir.

Many herpes viruses, including HSV-1, significantly up-regulate COX-2 and to a lesser degree COX-1. Virally induced upregulation of COX enzymes is important for efficient viral replication. COX inhibitors exhibit anti-herpetic properties. NSAIDS which act by inhibiting COX enzymes are effective in reducing the severity of primary herpes virus lesions and diminishing reactivation of latent infections.

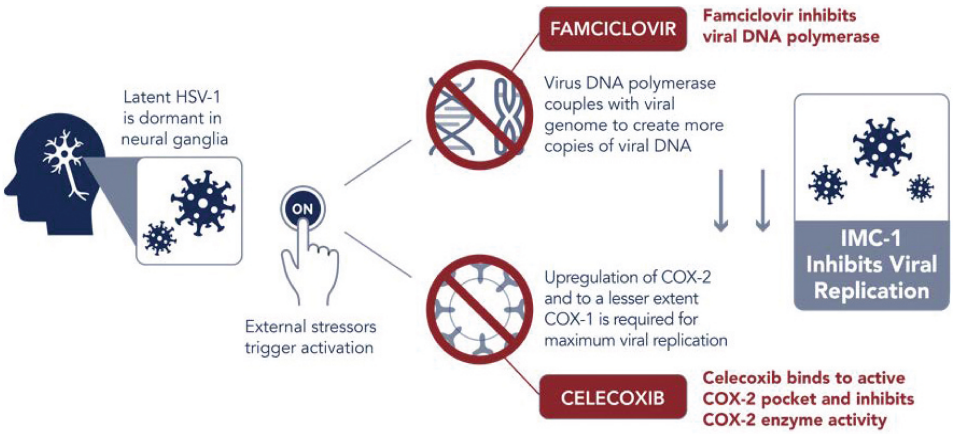
Celecoxib inhibits COX-2 and to a lesser degree COX-1, both of which are critical to the replication and growth of live virions. In general, COX-2 inhibition is regarded as more important than COX-1 inhibition for the suppression of HSV-1 reactivation. COX-2 activation is involved in the induction of 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. 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 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.

Dormant HSV-1 is Reactivated by External Triggers and Amplifies Its Own Replication via Cyclooxygenase (COX 1 and COX 2)



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



Our Experience Leads Us Down an Efficient Regulatory and Development Pathway

Since we are combining proprietary doses of two approved drugs, our fixed dose combination development candidate has the advantage of being 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 a New Drug Application ("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 would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for approved reference drug(s) with the same active ingredient(s). This unique approach enabled us to advance IMC-1 directly into a Phase 2a proof of concept study at a fraction of the cost of traditional drug development.

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. Following on from our successful Phase 2a trial, we held an end of Phase 2 meeting with the FDA and agreed to initiate a either a Phase 2b study or a Phase 3 program after we provide animal toxicology study data, conduct a human pharmacokinetic ("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 progress IMC-1 from Phase 2a proof-of-concept to a Phase 2b clinical trial of IMC-1 using optimized dosing of IMC-1 for the treatment of FM. We intend for this Phase 2b clinical trial to complement our Phase 2a study, while expanding the proofs and outcomes data. The Phase 2b and chronic toxicology studies are planned components of the registration package supporting Phase 3 requirements and will help to explore the potential of IMC-1 at optimized dosing as a precursor to transitioning to the Phase 3 clinical study and long term safety extension studies.

What is FM and why was it selected as the first disease target for IMC-1?

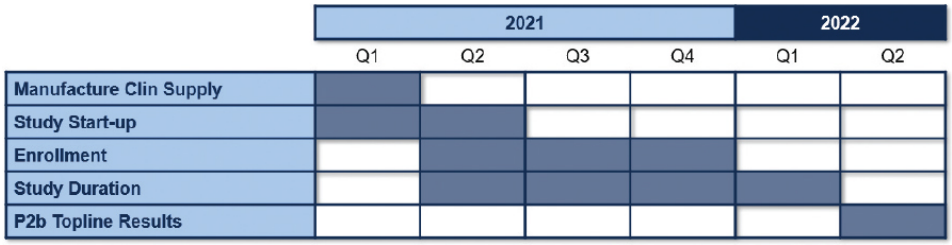
FM is a widespread chronic pain disorder including severe symptoms of fatigue that can last for 3 months or longer. It is also characterized by generalized aching, muscle stiffness, non-restorative sleep, chronic fatigue, depression, cognitive impairment and disturbances in bowel function. Researchers estimate that FM affects 2% to 8% of the US population and is the second most common "rheumatic disorder," second to osteoarthritis and the National Fibromyalgia & Chronic Pain Association estimates that 10 million Americans have FM.

FM was selected as the first disease target for IMC-1 based on several factors.

- The initial clinical signal of the potential for the synergistic combination of famciclovir and celecoxib was first derived through observation in patients in clinical practice. More specifically, patients diagnosed with IBS being treated with famciclovir, who were serendipitously also placed on celecoxib for their co-morbid arthritis, showed significant improvement not only in their IBS, but also exhibited less pain, fatigue, and headaches, the latter three of which are primary symptoms of FM. Following this observation, pre-planned targeted symptom tracking in open label clinical practice was conducted using famciclovir plus celecoxib to treat fibromyalgia, IBS and chronic fatigue. The founder then focused the primary development on fibromyalgia based on the following additional considerations, however, we believe IBS represents an encouraging opportunity for expanding the clinical utility of IMC-1.
- There is a very significant need for better FM therapies as reflected by the large untreated pool of currently diagnosed FM patients. Despite a very high disease burden, just over one in two (56%) patients currently diagnosed with FM are actively being treated with prescription medication. Furthermore, there are only three medicines approved to treat FM, reflecting limited treatment options available to FM patients. While effective at treating the pain component of FM, the three approved medications (pregabalin, duloxetine, and milnacipran) can give rise to a side-effect burden which limits their use.
- Even presently treated patients often have to manage the sub-optimal outcomes associated with using unapproved and/or potentially harmful medications to manage their FM disease. For example, almost 40% of FM patients are treated with opioids, despite well-established addictive properties, as well as published references highlighting worse FM treatment outcomes for opioid-treated patients as compared with FM patients not treated with opioids. Approximately 75% of the prescription medications used by FM patients are medicines not approved to treat FM.

Epidemiologic studies have shown that there are millions of patients worldwide suffering from FM, most of which are not presently diagnosed. We will focus our initial commercial efforts on raising the standard of care for patients presently diagnosed with FM. For example, in the US alone, it is estimated that 3.6 million patients are diagnosed with FM, and only 2 million of those patients are treated. We believe both treated and untreated diagnosed patients should be suitable targets for treatment with IMC-1. Following penetration of IMC-1 into the currently diagnosed segment of the market, we will commence market development activities to enhance both awareness and diagnosis of FM with the goal of growing the FM market and utilization of IMC-1 to treat FM over time.

FM Phase 2b Clinical Program Timelines Expected to Deliver Results in Q2 2022



Building out our Pipeline

In parallel to the Phase 2b fibromyalgia program, we plan to work with leading virologists to determine other diseases that are related to the activation of tissue resident viruses and are postulated to be a potential

root cause of the chronic illness, similar to the way herpes zoster is activated to cause shingles in older patients. Our goal is to identify multiple indications that could benefit by latent HSV-1 remaining dormant, such as IBS or functional somatic syndrome. The work below demonstrates that IBS is a good target and proof of concept studies using IMC-1 or one of our other patented NSAID/Antiviral combinations could be efficiently initiated by utilization of the 505(b)2 regulatory pathway.

Phase 2b IBS Trial Holds Potential to Build IMC-1 Value as a Complement to FM

Scientists at the University of Alabama conducted a GI biopsy study and determined that there is a strong correlation between HSV-1 upregulation and active FM and GI disturbance. A subset analysis of patients with pure GI disturbance further validates the potential connection between HSV-1 upregulation and the activation of IBS flare ups.

Unlike FM, where it is not feasible to biopsy neural ganglia where HSV-1 is resident, it is possible to biopsy gastrointestinal tissue in IBS patients using routine endoscopic procedures. This will enable us to demonstrate the presence of HSV-1 in an enriched sample of IBS patients. Our scientific team is presently engaged with leading gastroenterologists to develop a Phase 2 proof-of-concept study to demonstrate the efficacy and safety of IMC-1 for the treatment of IBS as a possible additional indication for IMC-1. We believe that the CMC and nonclinical studies that we have conducted to date in the FM program will also support this additional Phase 2 clinical work in IBS. We believe that we may use the 505(b)(2) regulatory pathway to enter directly into Phase 2 studies for IBS or other functional somatic syndrome conditions with IMC-1. We have not discussed the use of the 505(b)(2) regulatory pathway for these alternative indications with the FDA, but we will do so at the appropriate time.

Our Leadership Team

Our leadership team is now in place and is well positioned to continue advanced development of IMC-1 to treat FM. The newly expanded team has prior, direct leadership responsibility for both developing and commercializing two of the three medicines approved to treat FM. Greg Duncan, our CEO and Chairman, had direct management responsibility for Lyrica and Celebrex, the later being a component of IMC-1, during his tenure at Pfizer. Richard Burch, our current President, had direct responsibility for garnering FDA approval and subsequent commercialization of Lyrica during their tenures at Pfizer. Upon the completion of the Corporate Conversion, Mr. Burch will resign as President and will be appointed to our board of directors. Our Chief Medical Officer, Mike Gendreau, had primary responsibility for the development and approval of Savella and has served as an independent consultant to FDA in establishing approval standards for medicines seeking the indication for the treatment of FM. We are also guided by our board of directors and scientific advisory board. Our scientific advisory board is comprised of key scientific and clinical thought leaders in diseases associated with a viral triggered abnormal immune response.

Our Strategy

Our goal is to become a leading pharmaceutical company by improving the lives of patients by developing and commercializing novel therapies to treat diseases associated with a viral triggered abnormal immune response, with an initial focus on FM. The key elements of our strategy to achieve this goal include:

- ***Intelligently and efficiently advance the clinical development of our lead product candidate, IMC-1, for the treatment of FM, and proactively conduct Phase 3 clinical trial-enabling our transition to Phase 3, assuming success in our planned Phase 2b trial.***
    - In our proposed Phase 2b clinical trial of IMC-1 in FM patients, we are evaluating the ability of IMC-1 to reduce pain and fatigue and improve the overall global health status of patients diagnosed with FM. Additionally, we will assess the overall safety of IMC-1. We plan to enroll approximately 460 FM patients across approximately 40 sites located in the US, and expect to report top line results by Q2 2022.
    - Conduct chronic toxicology studies in rats and dogs for six and nine months, respectively to enable chronic administration of IMC-1, both in future research and to support commercialization.

- Manufacture adequate supplies of IMC-1 to support the planned Phase 2b trial, consistent with FDA standards for drug properties for Phase 3 and, if successful, commercialization.

- ***If approved, commercialize IMC-1 either independently or by collaborating with a partner, either globally or in selective geographies.***
  - Members of our leadership team have successful experience in both developing and commercializing two of the three medicines approved by FDA to treat FM (Lyrica and Savella).
  - We hold exclusive rights to develop and commercialize IMC-1 for all indications in the United States and other key territories.
  - We believe IMC-1, if approved for FM, can be initially commercialized with a targeted, specialist focused commercial infrastructure.
  - Based on initial uptake and the return on investment associated with this specialist focused approach, we will assess the optionality of expanding our commercial activities toward broader audience, including promotional activities focused on primary care providers.
  - Therefore, we plan to launch IMC-1 independently in North America, Europe and other key FM markets.
  - We may explore alternative development and commercialization partnership options if the planned IMC-1 FM Phase 2b study is successful, with the goal of maximizing probability of success and maximizing shareholder value.
  - We also intend to pursue the approval and commercialization of IMC-1 for follow-on indications, either alone or in partnership.

- ***Advance our ongoing exploratory research to support clinical development of IMC-1 for other virally mediated, chronic indications.***
  - Beyond FM, there are viral mediated immune response conditions with significant morbidity and mortality. These conditions include IBS, chronic fatigue syndrome and functional somatic syndrome, all of which are characterized by a waxing and waning manifestation of disease. There are limited options to address the underlying cause of these conditions, with most presently used medications treating the symptoms associated with these disease.
  - In contrast to FM, where biopsy of the nerve tissue where HSV-1 is resident is not practical, as demonstrated by our recently completed study, biopsy of GI tissue is quite feasible. This feasibility offers us the opportunity to recruit an enriched sample of IBS patients, all of who demonstrate evidence of HSV-1 activation via biopsy, as an efficient means to establish IMC-1's utility in IBS. Our scientific team is presently engaged with leading gastroenterologists to develop a Phase 2 IBS proof of concept study as a complement to the FM program.
  - If our exploratory work with several of the world's leading virologists reveals the potential of IMC-1 to treat patient populations in one or more of these rare inflammatory conditions, we intend to advance IMC-1 into Phase 2 clinical development to expand the value proposition of IMC-1 beyond FM.

Summary of Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. Some of these risks are:

- ***We have incurred significant net losses since inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.***
- ***Even if this offering is successful, we will require additional capital to fund our operations, and if we fail to obtain necessary funding, we may not be able to complete the development and commercialization of IMC-1.***
- ***We are heavily dependent on the success of IMC-1, our lead development candidate, which is still under clinical development, and if it does not receive regulatory approval or is not successfully commercialized, our business may be harmed.***

- ***We have received fast track designation for IMC; however, such fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor does it assure FDA approval of IMC-1.***
- ***We have concentrated our research and development efforts on the treatment of fibromyalgia, a disease that has seen limited success in drug development.***
- ***Clinical trials are expensive, time-consuming, difficult to design and implement, and involve an uncertain outcome.***
- ***Results of preclinical studies and early clinical trials may not be indicative of results obtained in later trials.***
- ***If we are unable to obtain, maintain and defend patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our target markets.***

Corporate Conversion

Immediately prior to the effectiveness of this registration statement, Virios Therapeutics, LLC converted into a Delaware corporation pursuant to a statutory conversion, and changed its name to Virios Therapeutics, Inc. In this prospectus, we refer to all transactions related to our conversion to a corporation as the Corporate Conversion. As a result of the Corporate Conversion, all members of Virios Therapeutics, LLC became holders of shares of common stock of Virios Therapeutics, Inc. The number of shares of our common stock that the members received in the Corporate Conversion was based on their relative rights as set forth in our limited liability company agreement. The purpose of the Corporate Conversion was to reorganize our structure so that the entity that is offering our common stock to the public in this offering is a corporation rather than a limited liability company and so that our existing investors will own our common stock rather than equity interests in a limited liability company. For further information regarding the Corporate Conversion, see "Corporate Conversion."

Our Corporate Information

We were initially formed as Innovative Med Concepts, LLC, an Alabama limited liability company, on February 28, 2012. On July 23, 2020 we changed our name to Virios Therapeutics, LLC. Prior to the closing of this offering, Virios Therapeutics, LLC converted into a Delaware corporation pursuant to a statutory conversion, and changed its name to Virios Therapeutics, Inc. See "Corporate Conversion." Our principal executive offices are located at 44 Milton Avenue, Alpharetta, GA 30009. Our telephone number is (866) 620-8655.

Our website address is *www.virios.com*. The information contained in, or accessible through, our website does not constitute a part of this prospectus.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a large accelerated filer, our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have irrevocably elected to take advantage of this extended transition period.

THE OFFERING

Common stock offered by us	3,000,000 shares
Common stock to be outstanding after this offering	7,832,494 shares (or 8,282,494 shares if the underwriters exercise their over-allotment option in full)
Over-allotment option	450,000 shares
Use of proceeds	We intend to use the net proceeds of this offering to advance the preclinical and clinical development of IMC-1 and for working capital and general corporate purposes. See "Use of Proceeds" in this prospectus for a more complete description of the intended use of proceeds from this offering.
Risk factors	See "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq symbol	"VIRI"

The number of shares of our common stock to be outstanding after this offering is based on 4,832,494 shares of our common stock outstanding as of December 16, 2020, after giving effect to the Corporate Conversion, the conversion of the $3,279,133 principal amount of our convertible promissory notes plus accrued interest that are outstanding as of the date hereof, and equity issuance for payment of accrued management salaries, which excludes:

- 292,500 shares of common stock issuable upon exercise of non-qualified stock options issuable to Mr. Burch pursuant to his employment agreement upon the closing of this offering at an exercise price equal to the offering price; and
- 812,500 shares of our common stock that are available for future issuance under our 2020 Equity Incentive Plan (of which options to purchase 487,500 shares of common stock will be issued upon the closing of this offering, or options to purchase 496,949 shares of common stock if the over-allotment is exercised in full).

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the completion of the Corporate Conversion as a result of which all outstanding membership interest of Virios Therapeutics, LLC will be converted into an aggregate of 4,342,299 shares of common stock of Virios Therapeutics, Inc.;
- the issuance of 425,333 shares of our common stock upon conversion of the $3,279,133 principal amount of our convertible promissory notes plus accrued interest through December 16, 2020 that are outstanding as of the date hereof;
- the issuance of 64,862 shares of our common stock upon this offering as payment for accrued management salaries;
- no exercise of warrants to purchase 29,629 shares of common stock at an exercise price of $7.80 per share, assuming an offering price of $10.00, which is the midpoint of the price range set forth on the cover of this prospectus, that expire on December 30, 2020;
- no exercise of warrants to purchase 105,044 shares of common stock at an exercise price of $7.80 per share, assuming an offering price of $10.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, that are exercisable for 30 days beginning on the date of the conversion of our outstanding convertible promissory notes;
- no exercise of outstanding options; and
- no exercise by the underwriters of their over-allotment option or the warrants to purchase 150,000 (172,500 if the over-allotment is exercised in full) shares of our common stock at an exercise price per share equal to 125% of the initial public offering price per share, or $12.50, that will be issued to the representative of the underwriters in connection with this offering (the "Representative's Warrants").

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2019 and December 31, 2018 from our audited financial statements appearing at the end of this prospectus. We have derived the statement of operations data for the nine months ended September 30, 2020 and 2019 and the balance sheet data as of September 30, 2020 from our unaudited interim financial statements appearing at the end of this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect, in the opinion of management, all adjustments of a normal, recurring nature that are necessary for a fair presentation of the unaudited interim financial statements. Our historical results are not necessarily indicative of results that should be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	Year Ended December 31,		Nine Months Ended September 30,	
(in thousands, except per share data)	2019	2018	2020	2019
			(Unaudited)	
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 836	$ 854	$ 162	$ 541
General and administrative	1,342	1,107	3,422	1,072
Total operating expenses	2,178	1,961	3,584	1,613
Loss from operations	(2,178)	(1,961)	(3,584)	(1,613)
Other income (expense)	(295)	(152)	(261)	(222)
Net loss	$ (2,473)	$(2,113)	$ (3,845)	$(1,835)
Pro forma net loss per common share – basic and diluted (unaudited)[(1)]	$ (0.51)		$ (0.80)	
Pro forma weighted average common shares outstanding – basic and diluted (unaudited)[(1)]	4,832,494		4,832,494	

(1) We have presented pro forma basic and diluted net loss per share which consists of our historical net loss attributable to Virios Therapeutics, LLC, divided by the pro forma basic and diluted weighted average number of shares of common stock outstanding after giving effect to (i) the Corporate Conversion, (ii) the conversion of the principal amount of outstanding convertible promissory notes plus accrued interest and (iii) the equity issuance for payment of accrued management salaries. See Note 2 to our audited financial statements and Note 2 to our unaudited interim financial statements included elsewhere in this prospectus for additional information regarding the method used to calculate the pro forma basic and diluted net loss per common share and the pro forma weighted average number of shares used in the computation of the per share amounts.

(in thousands)	As of September 30, 2020		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
	(Unaudited)	(Unaudited)	(Unaudited)
Balance Sheet Data:			
Cash	$ 499	$ 499	$ 27,132
Working capital	(1,224)	(438)	26,674
Total assets	785	785	27,193
Convertible promissory notes, net of unamortized deferred issuance costs	4,151	—	—
Preferred members' interests, non-voting, net	75	75	—
Equity (deficit)	(5,225)	(288)	26,674

(1) Reflects (i) the Corporate Conversion, (ii) the conversion of the principal amount of all outstanding convertible promissory notes plus accrued interest and (iii) the equity issuance for payment of accrued management salaries.

(2) Reflects (i) the effect of our issuance and sale of 3,000,000 shares of our common stock in this offering at an initial public offering price of $10.00 share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, (ii) the Corporate Conversion, (iii) the conversion of the principal amount of our convertible promissory notes plus accrued interest as of December 16, 2020, into shares of our common stock and (iv) the equity issuance and cash payment of accrued management salaries.

RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus 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 $2,473,627 and $2,113,592 for each of the years ended December 31, 2019 and 2018, and $3,845,167 and $1,835,038 for the nine month periods ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $21,463,877. 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.

Even if this offering is successful, 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.

We believe that the net proceeds from this offering together with our existing cash as of September 30, 2020, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 18 months. 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.

We, as well as our independent registered public accounting firm have expressed substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the years ended December 31, 2019 and 2018 and for the nine months ended September 30, 2020 and 2019 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. We believe that the net proceeds from this offering and our existing cash will be sufficient to fund our current operating plans through at least the next 18 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs and commercialization efforts.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, 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 prospectus 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, 2017 has generally not changed, tax losses generated in calendar year 2018 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 advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy

in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, 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 this Offering and Our Common Stock

No active trading market for our common stock currently exists, and an active trading market may not develop.

Prior to this offering, there has not been an active trading market for our common stock. If an active trading market for our common stock does not develop following this offering, 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 initial public offering price of our common stock will be determined by negotiations between us and the underwriters and may not be indicative of the market prices of our common stock that will prevail in the trading market.

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

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. The market price of our common stock may decline below the initial public offering price, and you may lose some or all of your investment.

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 will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We will have broad discretion in the application of the net proceeds from this offering and our shareholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. 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 this offering, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of this offering 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 this offering, 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 this offering 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 this offering will be 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 this prospectus. See "Shares Eligible for Future Sale — Lock-Up Agreements."

Our principal stockholders and management own a significant percentage of our stock and Richard Burch, our President and a director upon the closing, will receive stock options representing approximately 6% of our outstanding common stock immediately prior to the closing of this offering, and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 37.33% of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately 24.10% of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares), in each case giving effect to the Corporate Conversion. Additionally, Mr. Burch will receive nonqualified stock options, equal to approximately 6.0% of our outstanding shares immediately prior to the closing of this offering, or approximately 3.73% upon the closing of this offering. Therefore, even after this offering these stockholders will 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.

If you purchase shares of our common stock in this offering, you will incur immediate dilution in the book value of your shares.

The initial public offering price of our common stock will be substantially higher than the as adjusted net tangible book value per share of our common stock. Therefore, if you purchase our common stock in this offering, you will pay a price per share of our common stock that substantially exceeds the book value of our tangible assets after subtracting our liabilities. Based on the initial public offering price of $10.00 per share, you will experience immediate dilution of $6.59 per share, representing the difference between our net tangible book value per share, after giving effect to this offering, and the initial public offering price. Further, the future exercise of any outstanding options to purchase shares of our common stock will cause you to experience additional dilution. See "Dilution."

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.

In finalizing our financial statements for this offering, we identified a material weakness in our internal control over financial reporting related to the 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 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 this offering, (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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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 prospectus 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 prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. 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.

INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Information that is based on estimates, forecasts, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information based on various factors, including those discussed in “Risk Factors.”

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

We own or have rights to use a number of registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $27.0 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds will be approximately $31.1 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently anticipate that we will use the net proceeds from this offering, together with our existing resources, as follows:

- Conduct and complete the IMC-1 FM Phase 2b trial: This landmark trial will assess further optimized doses of IMC-1 and inform our Phase 3 program approach.
- Conduct and complete the IMC-1 chronic toxicology studies: Following on from our successful short-term toxicology studies, we will execute the required longer-term toxicology studies to support chronic administration of IMC-1 following our Phase 2b trial.
- Manufacture investigational drug for the Phase 2b study and for the chronic toxicology study. Refine clinical manufacturing process to conform with commercial standards to ensure if Phase 2b is successful and prepare to progress to Phase 3.
- Prepare and design Phase 2 IBS proof of concept study to expand the IMC-1 value proposition beyond FM.

The net proceeds from this offering, together with our cash, will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources. This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 18 months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

CORPORATE CONVERSION

Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, we converted Virios Therapeutics, LLC from an Alabama limited liability company to a Delaware corporation pursuant to a statutory conversion and changed our name to Virios Therapeutics, Inc. 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 our corporate structure so that the entity that is offering common stock to the public in this offering is a corporation rather than a limited liability company.

In conjunction with the Corporate Conversion, all of our outstanding membership interests, including membership interests issued to the holders of (i) convertible promissory notes with an aggregate principal amount of $1,465,000, plus accrued interest, on July 20, 2020, (ii) convertible promissory notes with an aggregate principal amount of $925,000, plus accrued interest, on November 30, 2020, and (iii) convertible promissory notes with an aggregate principal amount of $3,279,133, plus accrued interest, immediately prior to the Corporate Conversion, converted into an aggregate of 4,767,632 shares of our common stock. The number of shares of common stock issuable to each member in connection with the Corporate Conversion was determined pursuant to the applicable provisions of the plan of conversion. The holders of currently exercisable warrants have the ability to purchase 29,629 shares of common stock until December 30, 2020 at an exercise price of $7.80 per share. Upon the conversion of the outstanding convertible promissory notes, the note holders are entitled, for a period of 30 days thereafter, to exercise warrants to purchase 105,044 shares of common stock at a price of $7.80 per share.

As a result of the Corporate Conversion, Virios Therapeutics, Inc. succeeded to all of the property and assets of Virios Therapeutics, LLC and succeeded to all of the debts and obligations of Virios Therapeutics, LLC. Virios Therapeutics, Inc. is governed by a certificate of incorporation filed with the Delaware Secretary of State and bylaws, the material provisions of which are described under the heading “Description of Capital Stock.” On the effective date of the Corporate Conversion, each of our directors and officers will be as described elsewhere in this prospectus. See “Management.”

Except as otherwise noted herein, the Financial Statements included elsewhere in this prospectus are those of Virios Therapeutics, LLC and its operations. We do not expect that the Corporate Conversion will have an effect on our results of operations.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

CAPITALIZATION

The following table sets forth our cash and our capitalization as of September 30, 2020:

- on an actual basis;
- on a pro forma basis to give effect to (i) our Corporate Conversion and, in connection therewith, the conversion of all outstanding membership interests in our company issued and outstanding on September 30, 2020 into an aggregate of 4,221,260 shares of common stock, (ii) the issuance of 546,372 shares of our common stock upon conversion of the $4,204,133 principal amount of our convertible promissory notes plus accrued interest upon the closing of this offering, and (iii) the issuance of 64,862 shares of our common stock for payment of accrued management salaries upon the closing of this offering; and
- on a pro forma as adjusted basis, giving effect to the pro forma adjustments set forth above and to give further effect to our issuance and sale of 3,000,000 shares of our common stock in this offering at the initial public offering price of $10.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the following table together with our financial statements and the related notes appearing at the end of this prospectus and the "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock" sections of this prospectus.

	As of September 30, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash	$ 499	$ 499	$ 27,132
Convertible promissory notes	$ 4,151	$ —	$ —
Preferred members' interests, non-voting	$ 75	$ 75	$ —
Members' Equity (deficit):			
Membership interests, actual; none issued and outstanding, pro forma and pro forma as adjusted	$ 16,239	$ —	$ —
Stockholders' Equity (deficit):			
Common stock, $0.0001 par value; no shares authorized, and no shares issued and outstanding, actual; 43,000,000 shares authorized, pro forma and pro forma as adjusted; 4,832,494 shares issued and outstanding, pro forma; 7,832,494 shares issued and outstanding, pro forma as adjusted	$ —	$ 0	$ 1
Preferred stock, $0.0001 par value; no shares authorized, and no shares issued and outstanding, actual; 2,000,000 shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted	$ —	$ —	$ —
Additional paid-in capital	$ —	$ 21,176	$ 48,137
Accumulated deficit	$(21,464)	$ (21,464)	$ (21,464)
Total members' / stockholders' equity (deficit)	$ (5,225)	$ (288)	$ 26,674
Total capitalization	$ (999)	$ (213)	$ 26,674

The table above assumes no exercise of the underwriters' over-allotment option or the exercise of the Representative Warrants and does not include 292,500 shares of common stock issuable upon exercise of non-qualified stock options issuable upon the closing of this offering, warrants to purchase 134,673 shares of common stock at an exercise price of $7.80 per share, that will become exercisable upon the conversion of the outstanding convertible notes and 812,500 shares of our common stock that are available for future issuance under our 2020 Equity Incentive Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Pro forma net tangible book value per share represents the book value of our tangible assets less the book value of our total liabilities divided by the number of shares of common stock then issued and outstanding after giving effect to the Corporate Conversion.

Our historical net tangible book value deficit as of September 30, 2020 was $5.4 million, or $(1.27) per share of our common stock. Historical net tangible book value deficit per share represents our historical net tangible book value deficit divided by the 4,221,260 shares of our common stock outstanding as of September 30, 2020, after giving effect to the Corporate Conversion as if it occurred on September 30, 2020.

Our pro forma net tangible book value deficit as of September 30, 2020, was $.4 million, or $(0.09) per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving further effect to (i) the conversion of the $4,204,133 principal amount of our convertible promissory notes plus accrued interest upon the closing of this offering and (ii) the equity issuance for payment of accrued management salaries upon the closing of this offering.

After giving further effect to our issuance and sale of 3,000,000 shares of our common stock in this offering at the initial public offering price of $10.00 per share, and after deducting estimated underwriting discounts and commissions, our pro forma as adjusted net tangible book value as of September 30, 2020 would have been $26.7 million, or $3.41 per share. This represents an immediate increase in pro forma net tangible book value per share of $3.50 to our existing stockholders and immediate dilution in net tangible book value per share of $6.59 to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$10.00
Historical net tangible book value deficit per share as of September 30, 2020	$(1.27)	
Increase in pro forma net tangible book value per share attributable to the conversion of outstanding convertible promissory notes	$ 1.18	
Pro forma net tangible book value deficit per share as of September 30, 2020	$(0.09)	
Increase in pro forma as adjusted net tangible book value per share attributable to this offering	$ 3.50	
Pro forma as adjusted net tangible book value per share after this offering		$ 3.41
Dilution per share to new investors purchasing common stock this offering		$ 6.59

If the underwriters' over-allotment option is exercised in full, our pro forma as adjusted net tangible book value per share after this offering would be $3.73 and dilution per share to new investors purchasing common stock in this offering would be $6.27 at the initial public offering price of $10.00 per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2020, on a pro forma as adjusted basis, the total number of shares of common stock purchased from us on an as converted to common stock basis and the total consideration paid or to be paid and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at the initial public offering price of $10.00 per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing our common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
			(in thousands)		
Existing stockholders	4,832,494	61.7%	$17,211	36.5%	$ 3.56
New investors	3,000,000	38.3%	$30,000	63.5%	$ 10.00
Total	7,832,494	100%	$47,211	100%	

The table above assumes no exercise of the underwriters' over-allotment option or any Representative's Warrants. If the underwriters' over-allotment option is exercised in full, upon completion of this offering, the percentage of common stock held by existing stockholders would be reduced to 58.3%, and the percentage of common stock held by new investors purchasing common stock in this offering would be increased to 41.7%.

The tables above do not include (i) 292,500 shares of common stock issuable upon exercise of non-qualified stock options issuable upon the closing of this offering, (ii) warrants to purchase 134,673 shares of common stock at an exercise price of $7.80 per share, of which warrants to purchase 29,629 shares of common stock are currently exercisable until December 30, 2020 and warrants to purchase 105,044 shares of common stock that will become exercisable upon the conversion of the outstanding convertible promissory notes and (iii) 812,500 shares of our common stock that are available for future issuance under our 2020 Equity Incentive Plan.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statement of operations data for the years ended December 31, 2019 and 2018 from our audited financial statements appearing at the end of this prospectus. We have derived the statement of operations data for the nine months ended September 30, 2020 and 2019 and the balance sheet data as of September 30, 2020 from our unaudited interim financial statements appearing at the end of this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect, in the opinion of management, all adjustments of a normal, recurring nature that are necessary for a fair presentation of the unaudited interim financial statements. Our historical results are not necessarily indicative of results that should be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	Year Ended December 31,		Nine Months Ended September 30,	
(in thousands, except for per share data)	**2019**	**2018**	**2020**	**2019**
			(Unaudited)	
Statement of Operations Data:				
Operating expenses:				
Research and development	$ 836	$ 854	$ 162	$ 541
General and administrative	1,342	1,107	3,422	1,072
Total operating expenses	2,178	1,961	3,584	1,613
Loss from operations	(2,178)	(1,961)	(3,584)	(1,613)
Other income (expense)	(295)	(152)	(261)	(222)
Net loss	$ (2,473)	$(2,113)	$ (3,845)	$(1,835)
Pro forma net loss per common share – basic and diluted (unaudited)[1]	$ (0.51)		$ (0.80)	
Pro forma weighted average common shares outstanding – basic and diluted (unaudited)[1]	4,832,494		4,832,494	

(1) We have presented pro forma basic and diluted net loss per share which consists of our historical net loss attributable to Virios Therapeutics, LLC, divided by the pro forma basic and diluted weighted average number of shares of common stock outstanding after giving effect to (i) the Corporate Conversion, (ii) the conversion of the principal amount of all outstanding convertible promissory notes plus accrued interest and (iii) the equity issuance for payment of accrued management salaries. See Note 2 to our audited financial statements and Note 2 to our unaudited interim financial statements included elsewhere in this prospectus for additional information regarding the method used to calculate the pro forma basic and diluted net loss per common share and the pro forma weighted average number of shares used in the computation of the per share amounts.

	As of September 30, 2020		
(in thousands)	**Actual**	**Pro Forma[1]**	**Pro Forma As Adjusted[2]**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**
Balance Sheet Data:			
Cash	$ 499	$ 499	$ 27,132
Working capital	(1,224)	(438)	26,674
Total assets	785	785	27,193
Convertible promissory notes, net of unamortized deferred issuance costs	4,151	—	—

(in thousands)	As of September 30, 2020		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2]
	(Unaudited)	(Unaudited)	(Unaudited)
Preferred members' interests, non-voting, net	75	75	—
Equity (deficit)	(5,225)	(288)	26,674

(1) Reflects (i) the Corporate Conversion, (ii) the conversion of the principal amount of all outstanding convertible promissory notes plus accrued interest and (iii) the equity issuance for payment of accrued management salaries.

(2) Reflects (i) the effect of our issuance and sale of 3,000,000 shares of our common stock in this offering at the initial public offering price of $10.00 share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, (ii) the Corporate Conversion, and (iii) the conversion of the principal amount of our convertible promissory notes plus accrued interest as of December 16, 2020, into shares of our common stock and (iv) the equity issuance and cash payment of accrued management salaries.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion summarizes the significant factors affecting the operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with "Prospectus Summary — Summary Financial Information," "Selected Financial Information" and the financial statements and the related notes thereto included elsewhere in this prospectus. The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and all other non-historical statements in this discussion are forward-looking statements and are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this prospectus, particularly in the section entitled "Risk Factors."

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 Herpes Simplex Virus-1 ("HSV-1") has been postulated to be a potential root cause of chronic illnesses such as fibromyalgia ("FM"), irritable bowel disease ("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, which we have named IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination 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 and thus inhibits upregulation of the HSV-1 virus. The celecoxib component of IMC-1 inhibits cyclooxegenase-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 combination therapy generated a result that is greater than the sum of its parts.

We currently operate as an Alabama limited liability company under the name Virios Therapeutics, LLC. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, we will convert Virios Therapeutics, LLC from an Alabama limited liability company to a Delaware corporation pursuant to a statutory conversion and change its name to Virios Therapeutics, Inc. As a result of the corporate conversion, all of the membership interests held by the existing members of Virios Therapeutics, LLC will be converted into shares of common stock.

We have never been profitable and have incurred losses since inception. Our net losses were $2,473,627 and $2,113,592 for the years ended December 31, 2019 and 2018, respectively. Our net losses for the nine months ended September 30, 2020 and 2019 were $3,845,167 and $1,835,038, respectively, and our accumulated deficit at September 30, 2020 was $21,463,877. 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 state 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-based compensation, for personnel in executive, finance, operations and administrative functions. Other significant costs include costs not otherwise included in research and development expenses such as business development costs, legal fees relating to corporate matters, and fees for accounting, tax and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, 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. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or the SEC, requirements, director and officer insurance costs and investor and public relations costs.

Other Income (Expense), Net

Other income (expense), net, primarily consists of interest expense on the outstanding convertible promissory notes and the outstanding redeemable preferred convertible interests.

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 prospectus, 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-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.

Results of Operations

Operating expenses were comprised of the following:

	Year Ended December 31,		Nine Months Ended September 30,	
	2019	2018	2020	2019
			(Unaudited)	
Research and development	$ 836,175	$ 854,109	$ 161,944	$ 541,073
General and administrative	1,342,324	1,107,386	3,421,798	1,071,696
	$2,178,499	$1,961,495	$3,583,742	$1,612,769

Years Ended December 31, 2019 and 2018

Research and Development Expenses

Research and development expenses decreased by $17,934, or .02%, to $836,175 for the year ended December 31, 2019 from $854,109 for the year ended December 31, 2018. The decrease was primarily the result of a $638,000 decrease in contract development and manufacturing organization costs offset by a $625,000 increase in contract research organization costs. All of the research and development expenses for the years ended December 31, 2019 and 2018 were external.

General and Administrative Expenses

General and administrative expenses increased by $234,938, or 21.2%, to $1,342,324 for the year ended December 31, 2019 from $1,107,386 for the year ended December 31, 2018. The increase was primarily the result of a $262,000 increase for business development, market study and D&O insurance offset by a $19,000 decrease in travel related expenses.

Nine Months Ended September 30, 2020 and 2019

Research and Development Expenses

Research and development expenses decreased by $379,129 or 70.1% to $161,944 for the nine months ended September 30, 2020 from $541,073 for the nine months ended September 30, 2019. The decrease was

primarily the result of a decrease in CRO costs and related consulting of $365,000 for the PK Study in 2019, an $8,000 decrease in drug development costs, a $4,000 decrease in regulatory consulting and $3,000 decrease in research consulting. All of the research and development expenses for the nine months ended September 30, 2020 and 2019 were external.

General and Administrative Expenses

General and administrative expenses increased by $2,350,102 or 219.29% to $3,421,798 for the nine months ended September 30, 2020 from $1,071,696 for the nine months ended September 30, 2019. The increase was primarily the result of an increase in compensation expense of $2,000,000 for an aggregate issuance of 5% membership interests to the founder, salaries and benefits of $526,000, accounting, tax and auditing fees of $129,000, legal fees of $163,000 and filing fees of $16,000 offset by a decrease in guaranteed payments of $219,000 and a decrease in marketing and business development costs of $259,000.

Liquidity and Capital Resources

Since our inception in 2012, we have devoted most of our cash resources to research and development and general and administrative activities. We have financed our operations primarily with the proceeds from the sale of membership interests and convertible promissory notes. 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 September 30, 2020, our principal source of liquidity was our cash, which totaled $499,082.

Financings

For the year ended December 31, 2019, we received net proceeds of $2,371,508 from the sale of convertible promissory notes. For the year ended December 31, 2018, we received net proceeds of $1,150,468 from the sale of redeemable preferred convertible interests. For the nine months ended September 30, 2020 and 2019, we received net proceeds of $1,936,162 and $1,803,803, respectively, from the sale of convertible promissory notes. In addition, the Company capitalized $13,527 of offering costs relating to a capital raise not closed by September 30, 2019.

Debt

In 2019, we issued an aggregate of $3,675,000 principal amount of convertible promissory notes, $1,245,000 of which were related to the conversion of redeemable preferred convertible interests that were issued in 2018. All of the notes were outstanding for the year ended December 31, 2019. For the nine months ended, September 30, 2020, we issued an aggregate of $1,994,133 principal amount of convertible promissory notes. These notes will convert to common interests that results in the greater ownership percentage of the price issued in connection with this offering or at the price of $400,000 per 1 % of common interests. Regardless of the price per membership interest used in this offering, the notes shall convert into common interests at a rate no less than 1% per $400,000 of preferred interests, placing a cap on the valuation of the Company at $40,000,000 for the purposes of the conversion, even if the IPO offering is higher. There was no debt outstanding for the year ended December 31, 2018.

Non-voting Preferred Members' Interest

In 2018, we sold an aggregate of $1,320,000 of redeemable preferred members' interests. In 2019, $1,245,000 of the redeemable preferred members' interests were converted into convertible promissory notes. The principle of the preferred members' interests will be repaid upon the closing of this offering. For the years ended December 31, 2019 and 2018, there were principle amounts outstanding of $75,000 and $1,320,000, respectively. For the nine months ended, September 30, 2020 and 2019, there were principle amounts outstanding of $75,000 and $780,000, respectively.

Future Capital Requirements

We expect that the net proceeds from this offering and our existing cash will be sufficient to fund our operations and capital requirements for at least the next 18 months. 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.

Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we make in the future. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. We may need to raise substantial additional capital in order to engage in any of these types of transactions.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company following the closing of this offering.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the initiation, progress, timing, costs and results of clinical trials for our product candidates;
- the clinical development plans we establish for our product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the DEA, the FDA, the EMA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- costs and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

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.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and 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. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Cash Flows

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

	Years Ended December 31,		Nine Months Ended September 30,	
	2019	2018	2020	2019
			(Unaudited)	
Statement of Cash Flows Data:				
Total net cash (used in) provided by:				
Operating activities	$(2,092,150)	$(1,195,955)	$(1,608,834)	$(1,620,436)
Financing activities	2,371,508	1,150,468	1,798,532	1,797,078
Increase (decrease) in cash	$ 279,358	$ (45,487)	$ 189,698	$ 176,642

Years ended December 31, 2019 and 2018

Operating Activities

For the year ended December 31, 2019, cash used in operations was $2,092,150 compared to $1,195,955 for the year ended December 31, 2018. The increase in cash used in operations was primarily the result of the increase in net loss for 2019. We expect cash used in operating activities to continue to increase in 2020 as compared to 2019 due to an expected increase in our operating losses associated with ongoing development of our product candidate.

Financing Activities

Cash provided by financing activities was $2,371,508 during the year ended December 31, 2019, attributable to $2,430,000 from the sale of convertible promissory notes partially offset by the payment of $23,537 of deferred issuance costs and $34,955 of fees on the issuance of the convertible promissory notes. Cash provided by financing activities was $1,150,468 during the year ended December 31, 2018, attributable to $1,220,000 from the sale of non-voting preferred members' interests partially offset by the payment of $42,043 of deferred issuance costs and $27,489 of fees on the issuance of the convertible promissory notes.

Nine Months Ended September 30, 2020 and 2019

Operating Activities

For the nine months ended September 30, 2020, cash used in operations was $1,608,834 compared to $1,620,436 for the nine months ended September 30, 2019. The decrease in cash used in operations was primarily the result of an increase in accounts payable and accrued expense balances offset by an increase in prepaid expenses and other current assets.

Financing Activities

Cash provided by financing activities was $1,798,532 for the nine months ended September 30, 2020, attributable to the $1,994,133 proceeds from the sale of convertible promissory notes partially offset by the payment of $57,971 fees on the issuance of the convertible promissory notes and the $137,630 payment of deferred offering costs related to this offering. Cash provided by financing activities was $1,797,078 for the nine months ended September 30, 2019, attributable to $1,850,000 from the sale of convertible promissory notes partially offset by the payment of $23,537 of deferred issuance costs and $29,385 of fees on the issuance of the 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 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 is evaluating the impact of the pronouncement on its financial statements and does not expect the adoption of this pronouncement to have a material impact.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash.

We currently have no operations outside the United States, but we have contracted with third parties to manufacture our product candidates and conduct clinical trials outside of the United States. At this time, such manufacturing and research costs are paid for in U.S. dollars and, therefore, are not subject to fluctuations in exchange rates. If we conduct additional clinical trials outside of the United States in the future, we may be required or may choose to pay for those clinical trials in a local foreign currency and could incur foreign currency exchange rate risk.

We do not engage in any hedging activities against changes in interest rates or foreign currency exchange rates. Because of the short-term maturities of our cash, we do not believe that an immediate 10% increase in interest rates would have any significant impact on the realized value of our investments.

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.

FOUNDER'S VISION

No vision statement can be complete without a look backwards toward the motivation and the "Aha!" moments that gave rise to the formation of the company. Medicine is not an exact science and there remain gaping holes in our understanding of the multitude of medical conditions that plague mankind. My practice of medicine exposed me to countless patients who suffered from abdominal pain, and many who also suffered from chronic widespread pain as well. I learned that a combination of a COX-2 inhibitor and a nucleoside analogue (antiviral agent), may have the ability to reverse the pain and symptoms of many chronic gastrointestinal symptoms, and could possibly alleviate the widespread pain of fibromyalgia (FM). I realized at that moment, that we might have just potentially filled in one of those gaping holes of modern medicine. I then formed this company, and we set out to prove that patients with a certain genetic predisposition, who suffer from FM, after having been exposed to significant life stressors will develop a chronic abnormal stress or immune response to Herpes-Simplex Virus 1 (HSV-1).

Our primary focus is on improving overall outcomes for FM patients. FM represents a huge global unmet medical need. It has been estimated that there are more people globally infected with HSV-1, than those not infected with HSV-1. Initial HSV-1 exposure can lead to a primary infection, such as oral herpes ulcers, and new evidence of an ever-increasing percentage of HSV-1 genital herpetic infections. Once the primary infection has resolved, the virus lies dormant until an external stressor activates the virus. In the past, the lack of scientific understanding about an underlying root cause for FM, combined with the absence of appropriate diagnostic tools, has led to a "cocktail" treatment approach.

We are developing our lead candidate, IMC-1, so that it interrupts the reactivation and amplification of the viral immune response. This results in a suppression of HSV-1 into dormancy, thus turning off the abnormal chronic immune response. Because IMC-1 is believed to reverse the underlying cause of FM, our trial data also demonstrated an improvement in fatigue and depression, conditions often experienced by FM patients. It also revealed that the patients had a better overall feeling of wellness. We are proud that our creative problem-solving abilities coupled with important clinical observations made possible a well-designed, "Proof of Concept" Phase 2 FM Trial. We executed a rigorous, randomized, double-blinded, placebo-controlled clinical trial format, and while we focused on IMC-1's ability to treat the pain of FM, we were equally proud that we met statistical significance in nearly all secondary endpoints as well.

Our executive team and our support network are very familiar with the development and commercialization of FM treatments, and we remain hyper-focused on the IMC-1 drug development program. The support network includes key opinion leaders in FM and virology expert collaborators, who are equally passionate about ensuring better care for patients suffering virally mediated debilitating diseases. We will harness their expertise, which should help us expand future indications for paradigm-changing treatments in IBS, Myalgic Encephalomyelitis Chronic Fatigue Syndrome (ME/CFS) and other potential indications. We are also mindful, however, of the risks that we will face in all stages of the drug development and indication acquisition process.

Please join us in our journey as we seek to develop drugs to mitigate the effects of virally mediated, highly debilitating, chronic diseases affecting hundreds of millions of victims worldwide.

William L. Pridgen, MD
Founder, Virios Therapeutics, LLC

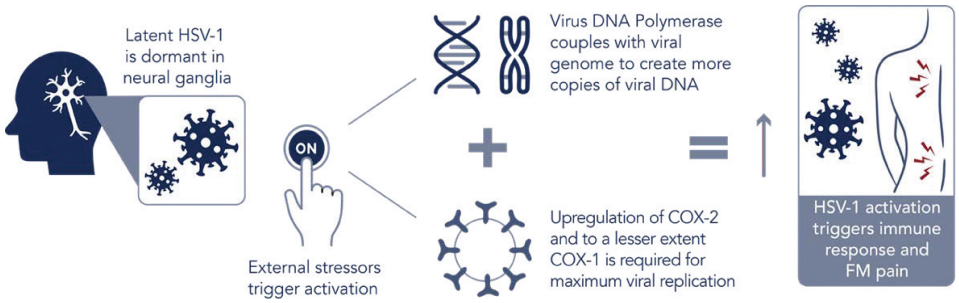
BUSINESS

Our Company

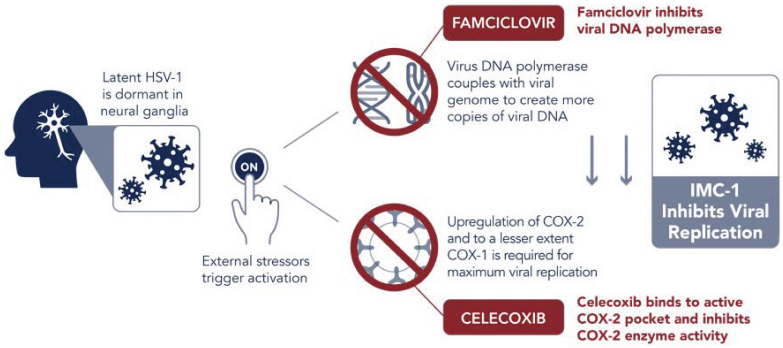
We are a development-stage biotechnology company focused on advancing novel antiviral therapies to treat diseases associated with a viral triggered abnormal immune response such as FM. Overactive immune response related to activation of tissue resident Herpes Simplex Virus-1 ("HSV-1") has been postulated to be a potential root cause of chronic illnesses such as fibromyalgia ("FM"), irritable bowel disease ("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. IMC's lead candidate, which we have named IMC-1, is a novel, proprietary, fixed dose combination of famciclovir and celecoxib. IMC-1 represents a novel combination 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 and thus inhibits upregulation of the HSV-1 virus. The celecoxib component of IMC-1 inhibits cyclooxegenase-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 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)

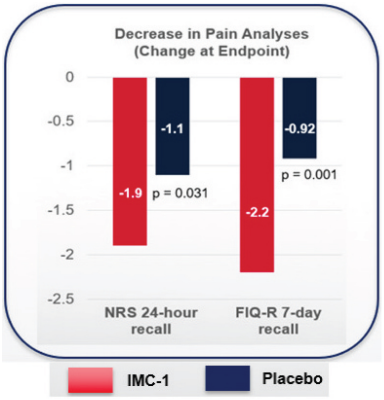


IMC-1's Novel, Synergistic Antiviral Mechanism Suppresses Viral Replication, Demonstrates FM Treatment Effect



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,

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 at least the last for up to 3 months or longer. It 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 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 ≥ 7 and SSS score ≥ 5 OR WPI = 4-6 and SSS score ≥ 9;
- Generalized pain, defined as pain in at least 4 of 5 regions, is present; and
- Symptoms have been present at a similar level for at least 3 months.

A diagnosis of 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

a. 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.

b. 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.

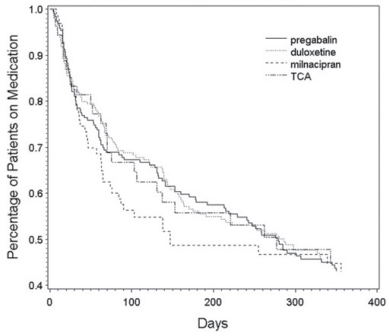
The table below shows the percentage use of different therapies for FM based on data from a 2012 study lead by Dr. Rebecca Robinson, a fibromyalgia researcher, and her colleagues. The study evaluated the burden of illness and treatment patterns for patients with fibromyalgia from July 2008 through May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

TIME TO DRUG DISCONTINUATION



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 where 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.

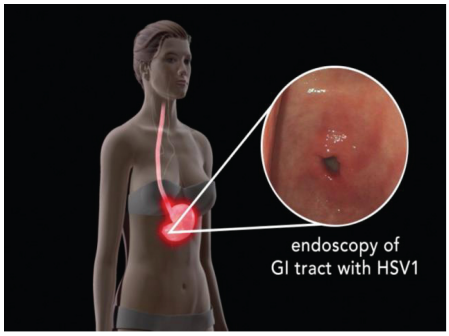
The anti-herpes virus MOA of the nucleoside analogs (which include famciclovir) is well characterized and this drug class has been used to treat viruses over decades. In its active state famciclovir is initially phosphorylated to a monophosphate form, after which it is converted to penciclovir triphosphate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

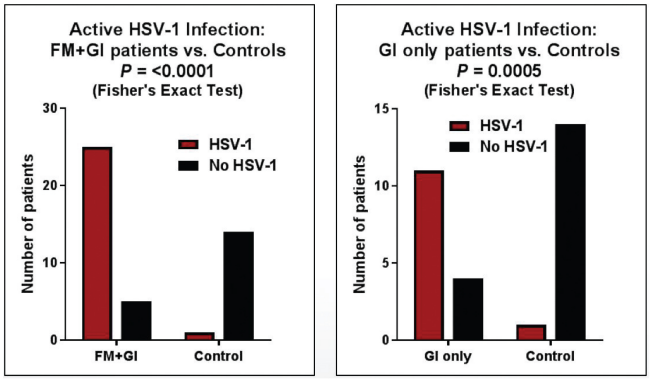
The initial clinical evidence supporting the development of an antiviral plus COX-2/NSAID combination to address FM was first derived through clinical observation in patients with IBS. IBS patients treated with famciclovir, who were serendipitously also placed on celecoxib to treat their arthritis, showed 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. 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. 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 Placebo N = 71	IMC-1 N = 66	Contrast (SE)	P- Value**
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 • 7 Day Recall NRS	 p=0.009 p=0.001
Pain Responder Analysis – **30% Pain Reduction** 24 Hour Recall NRS @ week 16 7 Day Recall NRS @ week 16	 p=0.052 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%)	0
Gastroesophageal Reflux Disease	4 (5.5%)	0
Alopecia	4 (5.5%)	0
Oropharyngeal Pain	4 (5.5%)	0

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.

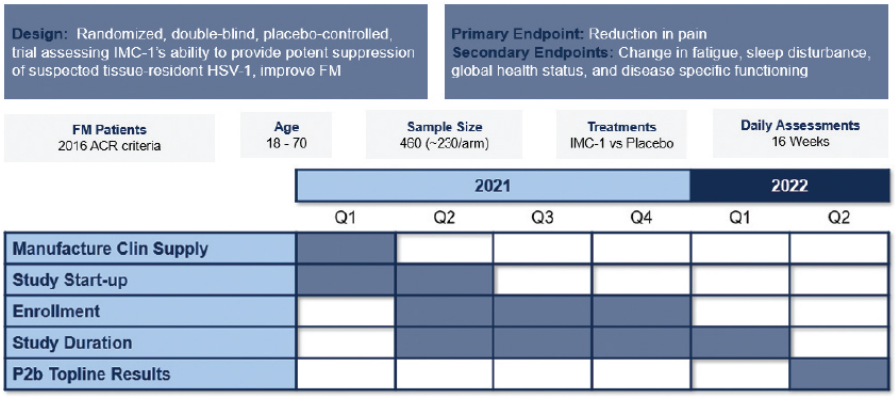
We have also successfully completed the required 90-day sub-chronic toxicology studies with the oral combination of IMC-1 that we believe support the optimal dosing to be used in the Phase 2b and Phase 3 trials. This GLP 13-week general toxicology study with toxico-kinetics and a recovery period has 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 form 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. 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 approximately 40% of FM patients take opioids.

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 2019 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 2019 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.

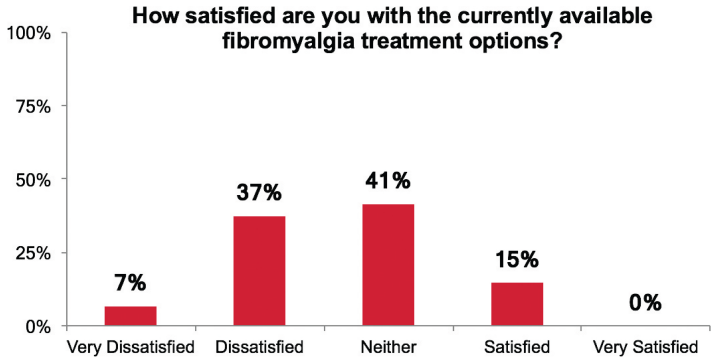
Primary Research Background

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.

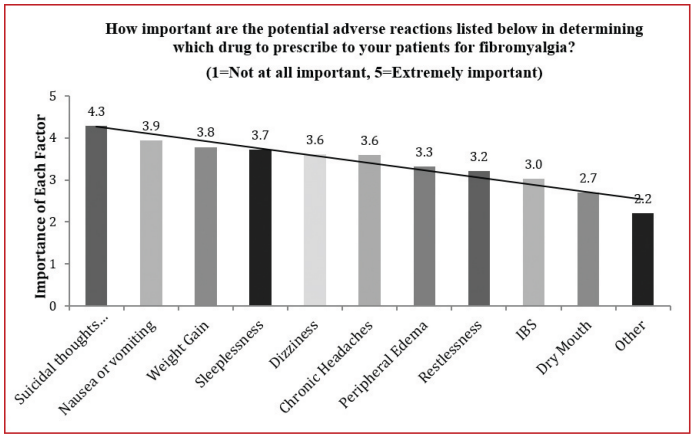
This primary research confirmed the large unmet medical need in the treatment of FM. The researchers found that physicians and patients, express a need for additional, safer and more efficacious FM therapy options. The 2014 assessment found that only 15% of the 75 physicians surveyed expressed satisfaction 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. As seen below, physicians noted that these adverse reactions influence their decision as to which drugs to prescribe.

Effect of Adverse Reactions on Prescribing



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 2019 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.

Summary of active FM research programs:

Compound	MoA	Dev Stage	Commentary
NYX-2925 (Aptynx)	NMDA receptor modulator	Phase 2 ongoing Results in 2021	CNS mediated, pain modulator
TON-102	Sub-lingual cyclobenzapine	Phase 3 ongoing Two prior failed FM studies	Focused on sleep quality improvement, with improvement in FM
ASB0819 (Astellas)	Ca2 activated K channel opener	Phase 2 Completed 2018	No data released
Teva (NCT03965091)	MAB Administered Sub-cut monthly	Phase 2 ongoing Results 2H 2021	Approved for migraine, inferior delivery

Other Market Opportunities

Each of the 2014 and 2019 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 2019 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 November 12, 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.

Employees

As of September 30, 2020, we had 4 full-time employees and we contracted with 2 independent consultants. 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 matter.

Facilities

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

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.

MANAGEMENT

The following table sets forth the name, age as of the date of this prospectus, and position of the individuals who currently serve as directors and executive officers of Virios Therapeutics, LLC, and will serve as directors and executive officers of Virios Therapeutics, Inc. following the Corporate Conversion and the closing of this offering. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of our directors and executive officers as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

Name	Age	Position
Executive Officers		
Greg Duncan	55	Chief Executive Officer, and Chairman
Richard Burch[2]	64	President, Director
R. Michael Gendreau, M.D., Ph.D.	65	Chief Medical Officer
Ralph Grosswald	52	Vice President of Operations
Angela Walsh	54	Vice President of Finance, Treasurer
Directors		
Robert Buchalter[1]	64	Director
Abel De La Rosa, Ph.D.[3]	57	Director
David Keefer	67	Director
William L. Pridgen, M.D.	60	Founder, Director
John C. Thomas, Jr.[3]	67	Director
Richard J. Whitley, M.D.[3]	75	Director
Robert Young[1]	74	Director

(1) Will resign as a director in connection with the Corporate Conversion.

(2) Will resign as President and will be appointed a director in connection with the completion of the Corporate Conversion.

(3) Will be appointed a director in connection with the completion of the Corporate Conversion.

Executive Officers

Greg Duncan has been our Chief Executive Officer since April 1, 2020 and a director since 2018. Since November 2020, Mr. Duncan has served as a director of CorMedix Inc. (NYSE American: CRMD) a biopharmaceutical company focused on developing and commercializing therapeutic products for the prevention and treatment of infectious and inflammatory diseases. Previously, from January 2014 to March 2020, Mr. Duncan was President and Chief Executive Officer of Celtaxsys, Inc., a privately held biotech company focused on developing anti-inflammatory medicines for rare disease where he scaled the required capital to build out the organizational capability to advance both pre-clinical and clinical development candidates. Prior to Celtaxsys, from 2007 to 2013, Mr. Duncan served as an Executive Committee member at Belgium based UCB, a specialty pharma entity developing and commercializing medicines for immunologic and central nervous system disorders. Before joining UCB, from 1989 to 2007 Mr. Duncan, while at Pfizer he held several executive U.S. and international appointments, including President of Pfizer's $2B Latin America Operations and SVP of Marketing. His operational teams had accountability for the launches of many pharmaceutical brands including Lipitor, Zoloft, Viagra, Celebrex, Aricept, Lyrica, Cimzia, Zithromax (ZPack), Diflucan, Sutent, Rebif and Vimpat. Mr. Duncan has served as director for IMC, Biotie Therapeutics, the American Psychiatric Foundation, Bio International Organization (BIO), Southeast BIO (SEBIO and the Georgia Bio industry association groups. Greg holds a master's degree in business administration from Emory University in Atlanta, GA, and a bachelor's degree in economics from the State University of New York in Albany, NY. We believe that Mr. Duncan is qualified to serve on our board of directors due to his significant experience in the pharmaceutical industry and the development of candidates.

Richard Burch has been our President since January 2014. Prior to joining IMC, Mr. Burch worked at Pfizer from 1979 to 2009 starting as a sales rep and working his way up to Senior Vice President overseeing numerous divisions with more than 6,500 employees. He was accountable for $11.5 billion in revenue and had responsibilities in launching or managing over 20 pharmaceutical products, including blockbuster brands such as Celebrex, Lyrica, Aricept, Zoloft, Rebif, Zithromax and Lipitor. Following his tenure at Pfizer, Mr. Burch was named Vice President and General Manager for UCB, Inc., overseeing all operations for the US CNS Business Unit including P&L management and responsibility for pipeline and in-line portfolio of CNS products. Mr. Burch currently serves on the University of Alabama Business School Board and is a member of the University of Alabama President's Cabinet and on the Executive Committee for the DCH Health System Foundation Board. Mr. Burch received a Bachelor's Degree in Marketing from the University of Alabama and certification from the Finance and Accounting Department of Columbia University's Graduate School of Business. We believe that Mr. Burch is qualified to serve on our board of directors due to his significant experience as an executive in the pharmaceutical industry.

R. Michael Gendreau, M.D., Ph.D. has been acting Chief Medical Officer since 2012. Dr. Gendreau is presently a healthcare consultant specializing in biotechnology for Gendreau Consulting, LLC which he started in 2011. He received his B.S. in chemistry from Ohio University and his M.D./Ph.D. in medicine and pharmacology from The Ohio State University College of Medicine. Before starting his own consulting firm, R. Michael Gendreau worked at Cypress Bioscience, Inc. from 1995 to 2011. During that time, he held various positions including Vice President of Research and Development and Chief Medical Officer. Before joining Cypress Bioscience, Inc., Dr. Gendreau was Vice President of Research and Development and Chief Medical Officer for MicroProbe Corporation, a developer and manufacturer of DNA/RNA probe-based diagnostic products.

Ralph Grosswald has been the Vice President of Operations since April 1, 2020. Mr. Grosswald brings 25 years of experience developing innovative drugs and medical devices to our leadership team. Previously, Mr. Grosswald was a founder and Vice President of Operations at Celtaxsys, Inc. from August 2005 to March 2020 where he managed operations, nonclinical development and clinical trials of acebilustat for the treatment of cystic fibrosis. Prior to that, Mr. Grosswald started GMP Companies, Inc. where he managed development programs of the first ever Microinvasive Glaucoma Shunt and the LifeSync Wireless ECG from 1999 to 2005. Before joining GMP, from 1997 to 1999, he was the Director of Outcomes Research for the National Healthcare Network, a cardiovascular centers of excellence managed care network partnered with the Duke Clinical Research Institute. Mr. Grosswald began his career as a clinical trial coordinator for both interventional cardiology and cardiothoracic surgery studies at the Emory University School of Medicine from 1990 to 1997. Mr. Grosswald holds a Bachelor of Arts and a Master of Public Health degree from Emory University.

Angela Walsh has been the Vice President of Finance and Treasurer since April 1, 2020. Ms. Walsh has over three decades of experience in the field of financial management and accounting, specializing in mergers and acquisitions, strategic planning, compliance and risk management, financial modeling, budgeting, and forecasting. From March 2016 to March 2020, she was the VP of Finance for Celtaxsys, Inc. where she oversaw and managed the company's financial and accounting activities. Prior to that from 2015 to 2016, Ms. Walsh worked at Vennskap, LLC and from 2014 to 2015 was the CFO for Green Circle Bio Energy and was part of the executive team that executed a successful acquisition by Enviva Partners, LP, which subsequently executed a $214M initial public offering. From 2011 to 2014, she worked at Atlanco and from 2006 to 2011, she worked at Altea Therapeutics. From 2003 to 2006, she was the Controller for Huffy Sports, a division of the Russell Corporation and participated in numerous capital market transactions including mergers and acquisitions, debt offerings and filing S-1s for initial public offerings. Ms. Walsh began her accounting career with Arthur Anderson and is a Certified Public Accountant in both Georgia and North Carolina. Ms. Walsh holds a BS in Accounting from Wake Forest University.

Non-Employee Directors

Robert Buchalter, a director since 2018, is co-founder and managing principal of Capital Growth Properties, Inc. which he founded in 2007. He also served as past chairman of the Alabama Builders Political Action Committee, and was on the Stillman College President's Advisory Committee. Giving back is a top priority for Robert, and he is currently involved in numerous civic activities. He previously served

as the president for Big Brothers Big Sisters of Birmingham, where he also served as a board member. He was also a board member of the Tuscaloosa chapter of Big Brothers and Big Sisters. He served as a member of Executive Leadership Committee for the March of Dimes annual March for Babies, and previously served as a fundraising director for Boy Scouts of West Alabama. He is also very involved in Habitat for Humanity. A native of Tuscaloosa, Alabama, Robert received his bachelor's degree in business administration/corporate finance and marketing from the University of Houston.

Abel De La Rosa will be a director upon the completion of the Corporate Conversion. Dr. De La Rosa has been the chief executive officer and a board member of Antios Therapeutics since 2018 when he co-founded Antios. Dr. De La Rosa was a member of the board of directors of Celtaxsys, Inc. from 2012-2020. Also he was the Chief Scientific Officer of Drug Innovation Ventures at Emory (DRIVE) and the Emory Institute for Drug Development (EIDD) from 2012 to 2018, focused on the discovery and development of antiviral drugs for the treatment of viral diseases of unmet medical need and global concern. Prior to joining Emory University, Dr. De La Rosa was Senior Vice President of Business Development and Scientific Affairs at Pharmasset, from 2002 until its acquisition by Gilead Sciences (Nasdaq: GILD) for $11 billion in 2012, he was responsible for licensing, strategic transactions, and alliance management of collaborations and partnerships with pharmaceutical companies and universities. Prior to Pharmasset, Dr. De La Rosa held both scientific and business positions at Visible Genetics, Innogenetics, Boston Biomedica, and Digene. He is an inventor and author on several U.S. patents and publications relating to molecular diagnostic methods, techniques and therapeutics for infectious diseases and cancer. Dr. De La Rosa earned a Fogarty Fellowship and an Intramural Research Training Award Fellowship from the National Institutes of Health, where he completed post-doctoral training in the Laboratory of Biochemistry and the Laboratory of Pathology of the National Cancer Institute. He holds a Bachelor's Degree in Microbiology from the University of California, San Diego, and a Ph.D. in Microbiology from Miami University. We believe that Dr. De La Rosa is qualified to serve on our board of directors due to his significant knowledge and experience in the pharmaceutical industry and his experience as an officer and director in the pharmaceutical industry.

David Keefer, a director since 2018, is currently leading a technology company focused on enhancing health education and enablement. Mr. Keefer is a 30-year industry veteran with broad-based experience in leading commercial operations. In addition, he is engaged in the nutraceutical area with a healthy energy supplements and drinks company. Mr. Keefer has been a visionary leader in the health care industry with a proven track record of success. He is a seven-time winner of Pharma Voice's top 100 leaders in healthcare. Mr. Keefer has held executive roles at Biovail, Pharmacia, Pfizer, Wyeth and Publicis Health. Roles including CEO, Chief Global Development Officer, Chief Commercial Officer, and other commercial focused roles in marketing and communications. Most recently, Mr. Keefer had overall responsibility for Global Business Development for Publics Health, the world's largest global health focused organization offering marketing, communications and personal message delivery solutions to the life sciences market. We believe that Mr. Keefer is qualified to serve on our board of directors due to is his significant knowledge and experience in the pharmaceutical industry as an executive and a director.

William L. Pridgen, M.D. is our founder and has been a director since 2018. Dr. Pridgen is a board-certified surgeon practicing with Tuscaloosa Surgical Associates, P.C. in Tuscaloosa, Alabama. Dr. Pridgen obtained his B.S. in Biology from Rhodes College, attending the medical school and completing his surgical residency at the University of Tennessee College of Medicine. Dr. Pridgen is certified in general surgery and is a fellow of the American College of Surgeons. Dr. Pridgen has spent nearly 20 years searching for effective treatments in IBS, FM, and MECFS, and served as a physician and surgeon in the United States Navy for five years. We believe that Dr. Pridgen is qualified to serve on our board of directors due to him being the founder of this company and his significant knowledge and experience in the pharmaceutical industry and in treatments for FM.

John C. Thomas, Jr. will be a director upon the completion of the Corporate Conversion. Since 2018, Mr. Thomas has served as the Chief Financial Officer and Secretary of SmartPharm Therapeutics, Inc, a genetic research and development company. In late 2017, Mr. Thomas rejoined DemeRx, Inc., a privately held company developing non-additive treatments for drug addiction, as the Chief Financial Officer after previously being the Chief Financial Officer from 2010 to 2013. Since April 2014, Mr. Thomas has served as a director of NantKwest, Inc. (Nasdaq: NK) and is chairperson of the audit committee and a member of the compensation committee. From 2001 until 2018, Mr. Thomas served as Chief Financial Officer and

Secretary, and from 2001 to 2016 as a director of CorMatrix Cardiovascular, a privately held medical device company. He has also served as Chief Financial Officer, Secretary, and Director of Motion Reality, Inc., a motion capture and simulation company, since 1991. From 2012 until 2019, Mr. Thomas served as a director of Novelion Therapeutics, Inc. (formerly QLT, Inc.), a public company focused on rare diseases and was the Chairperson of their Audit and Risk Committee and Nominating and Governance Committee. During the past ten years, Mr. Thomas served as acting Chief Financial Officer for DemeRx, Inc., MRI Interventions, Inc., MiMedx Group, Inc., and DARA BioSciences and as a director of MRI Interventions, Inc. Between 1999 and 2012, Mr. Thomas served as a Trustee and subsequently the Chairman of the Finance Committee of The Walker School, a private school. Mr. Thomas is a Certified Public Accountant and graduated from the University of Virginia, McIntire School of Commerce. We believe that Mr. Thomas is qualified to serve on our board of directors due to his significant financial and accounting knowledge and experience serving on boards of directors of public companies.

Richard J. Whitley, M.D. will be a director upon the completion of the Corporate Conversion. Dr. Whitley is the Distinguished Professor, Loeb Scholar Chair in Pediatrics, and Professor of Pediatrics, Microbiology, Medicine and Neurosurgery at the University of Alabama at Birmingham. He is the Co-Director, Division of Pediatric Infectious Diseases; Vice-Chair, Department of Pediatrics; Senior Scientist, Department of Gene Therapy; Director for Drug Discovery and Development; Senior Leader, Comprehensive Cancer Center; Associate Director for Clinical Studies, Center for AIDS Research; and Co-Founder and Co-Director, Alabama Drug Discovery Alliance. Dr. Whitley is responsible for the National Institute of Allergy and Infectious Diseases (NIAID) Collaborative Antiviral Study Group and directs a center for drug discovery in the arena of emerging infections. He is a past President of the International Society of Antiviral Research and the Infectious Diseases Society of America, and currently chairs both the NIAID Recombinant DNA Advisory Council and the NIAID HIV Vaccine Data Safety and Management Board. Dr. Whitley has been a director of Gilead Sciences, Inc. (Nasdaq: GILD) since 2008 and served on Gilead's Scientific Advisory Board from 2003 to 2008. He is an elected member of the American Society of Clinical Investigation, the Association of American Physicians and an Honorary member of the Irish Academy of Science. We believe that Dr. Whitely is qualified to serve on our board of directors due to his significant knowledge and experience in the pharmaceutical industry and serving on boards of directors of public companies.

Robert Young, a director since 2018, is currently an owner of Owen Meredith & Sons, a fee based property management company located in Tuscaloosa, Alabama, where he has worked since 1995. Mr. Young is a 1971 graduate of Virginia Tech where he majored in business and accounting. His career has spanned more than 25 years in advertising and 25 years in real estate. He was an equity partner in the multi-state advertising company, Creative Displays, and founder of the Tuscaloosa/Atlanta based Outdoor Today.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Composition and Election of Directors

Our board of directors currently consists of five members, Greg Duncan, our Chairman, Robert Buchalter, David Keefer, William L. Pridgen, M.D., and Robert Young, each of whom serve as a director pursuant to the board composition provisions of our Second Amended and Restated Operating Agreement, or the Operating Agreement. The Operating Agreement will no longer be in effect upon the Corporate Conversion.

Upon completion of the Corporate Conversion, our certificate of incorporation and bylaws will be in effective and provide that our board of directors will be elected once a year. Our certificate of incorporation that will go into effect upon the completion of the Corporate Conversion will provide that the authorized number of directors may be changed only by resolution of the board of directors. In connection with the Corporate Conversion the size of our board of directors will be increased to seven directors. The Company anticipates that Robert Buchalter and Robert Young will resign from the board and Richard Burch, Abel De La Rosa, Ph.D., John C. Thomas, Jr. and Richard J. Whitley, M.D. will be appointed to the board upon completion of the Corporate Conversion.

In selecting board members, our board may consider many factors, such as personal and professional integrity, ethics and values; experience in corporate management, such as serving as an officer or former officer of a publicly held company; experience as a board member or executive officer of another publicly held company; diversity of expertise and experience in substantive matters pertaining to our business relative to other board members; and diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience.

Director Independence

Our board of directors has determined that directors Abel De La Rosa, Ph.D., David Keefer, William L. Pridgen, M.D., John C. Thomas, Jr. and Richard J. Whitley, M.D. do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of the director and that each of these directors is "independent" as that term is defined under the rules of Nasdaq. There are no family relationships among any of our directors or executive officers.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Director Nominations

The board of directors as a whole will consider director candidates recommended for nomination by our stockholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of stockholders (or, if applicable, a special meeting of stockholders). Our stockholders that wish to nominate a director for election to our board of directors should follow the procedures set forth in our bylaws.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, our board of directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Board Committees

Our board of directors has established three standing committees — audit, compensation and nominating and governance — each of which operates under a charter that has been approved by our board of directors. Upon our listing on Nasdaq, each committee's charter will be available under the Corporate Governance section of our website at *www.virios.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Audit Committee

Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements. We have adopted an audit committee charter, which details the principal functions of the audit committee, including:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

The members of our audit committee are Abel De La Rosa, Ph.D., David Keefer and John C. Thomas, Jr.. Mr. Thomas serves as chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable listing rules of Nasdaq, and meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq rules. Mr. Thomas qualifies as an audit committee financial expert under Item 407 of Regulation S-K.

Compensation Committee

Our compensation committee assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers. We have adopted a compensation committee charter, which details the principal functions of the compensation committee, including.

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our Chief Executive Officer and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" to the extent required; and
- preparing the annual compensation committee report required by SEC rules, to the extent required.

The members of our compensation committee are Abel De La Rosa, David Keefer and Richard J. Whitley, M.D. Mr. Keefer serves as the chairperson of the committee. Our board of directors has determined that each committee member is independent under the applicable Nasdaq rules, including the Nasdaq rules specific to membership on the compensation committee, and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

Nominating and Governance Committee

Our nominating and governance committee assists our board of directors in its oversight of our corporate governance principles. We have adopted a nominating and governance committee charter, which details the principal functions of the nominating and governance committee, including:

- identifying nominees for election to the board, consistent with the qualifications and criteria approved by the board;
- determining the composition of the committees of the board;
- recommending to the board the director nominees for the annual meeting of stockholders;
- developing, overseeing and making recommendations to the board regarding our corporate governance guidelines and procedures;
- establishing and monitoring a process of assessing the board's effectiveness; and
- overseeing the evaluation of the board.

The members of our nominating and governance committee are David Keefer and Richard J. Whitley, M.D. Dr. Whitley serves as the chairperson of the committee. Our board of directors has determined that each committee member is independent are independent under the applicable Nasdaq rules, including the Nasdaq rules specific to oversight of director nominations.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been our current or former officer or employee. None of our executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon our listing on Nasdaq, our code of business conduct and ethics will be available under the Corporate Governance section of our website at *www.virios.com*. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Legal Proceedings

We are not aware of any of our directors or officers being involved in any legal proceedings in the past 10 years relating to bankruptcy, insolvency or criminal proceedings (other than traffic and other minor offenses) or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

EXECUTIVE AND DIRECTOR COMPENSATION

As an emerging growth company under the JOBS Act we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," which require compensation disclosure for our principal executive officer and our most highly compensated executive officer (other than our principal executive officer) serving as an executive officer at the end of the most recently completed fiscal year. This section describes the executive compensation program in place for our named executive officers for the year ended December 31, 2019.

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below and the non-employee members of our board of directors. In 2019, our "named executive officers" and their positions were:

- William L. Pridgen, M.D., Founder and Chief Executive Officer
- Richard Burch, President

We did not have any other named executive officers as of December 31, 2019. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2019.

Name and Principal Position	Year	Salary ($)	Option Awards ($)	Total ($)
William L. Pridgen, M.D.[(1)]	2019	350,000	—	350,000
Chief Executive Officer				
Richard Burch	2019	350,000	—	350,000
President				

(1) Resigned as Chief Executive Officer, effective April 1, 2020.

Bonuses

Our named executive officers did not participate in an annual cash bonus program or receive bonuses for 2019.

Equity Compensation

Our named executive officers did not receive any equity compensation in 2019. In connection with this offering, we intend to adopt a 2020 Equity Incentive Award Plan, which we refer to as the 2020 Plan, in order to facilitate the grant of cash and equity incentives to our directors, employees and consultants (including our named executive officers) and to enable us to obtain and retain services of these individuals, which we believe is essential to our long-term success.

Retirement, Health and Welfare Plans

No other plans were covered by the Company in 2019.

Outstanding Equity Awards

There were no outstanding equity awards outstanding as of December 31, 2019.

Employment Agreements

Each of our named executive officers employment is "at will" and may be terminated at any time.

William L. Pridgen, M.D. Agreement

On July 15, 2020, we entered into an agreement with Dr. Pridgen 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 this offering we will pay the accrued salary in cash or equity, in our discretion. Any cash portion must be paid within 30 days of the closing of this offering. Any equity portion will be issued using an agreed upon valuation per the agreement and shall be considered issued immediately before the IPO. A salary advance of $100,000 paid to Dr. Pridgen in 2014 and 2015, will be offset against the cash portion or the equity portion at the option of Dr. Pridgen.

On August 19, 2020, our Board approved the acceleration of the issuance of a 4.5% membership interest to Dr. Pridgen that was contemplated in the Virios Therapeutics Operating Agreement. The grant of the interest was completed to reduce the dilution applicable to current members and in anticipation of the Corporate Conversion.

Richard Burch Employment Agreement

On March 3, 2015, we entered into an employment agreement with Mr. Burch setting forth the terms of his employment as our President. Pursuant to the agreement, Mr. Burch is entitled to an annual base salary of $350,000, which amount is subject to annual review by and at the sole discretion of our board of directors or the compensation committee.

The employment agreement has a term commencing on the date thereof and continuing until terminated (i) upon death of the employee, (ii) upon disability, (iii) for cause, (iv) with good reason or without cause, or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection with his employment; (ii) paid vacation leave; and (iii) health benefits.

Mr. Burch is also entitled to receive cash and in-kind bonuses in connection with an incentive event (as defined in the employment agreement). Mr. Burch is entitled to receive a certain percentage (the "Incentive Event Payment") of the gross amount of cash, cash-like items, or publicly tradeable stock in the event of: (i) a successful and closed sale or license of a pharmaceutical product, compound, molecule, composition, or other property developed by the Company; (ii) a sale of (1) all or substantially all the assets of the Company; (2) a majority of the equity interests of the Company; or (3) a majority of the equity interests of the Company such that the Company is no longer controlled directly or indirectly by Dr. William Pridgen; or (iii) a merger or consolidation of the Company. Upon the termination of Mr. Burch's employment without cause, death, disability or by Mr. Burch for good reason, Mr. Burch is entitled to receive a portion of the Incentive Event Payments called for in the employment agreement prorated for the term of Mr. Burch's employment beginning on the effective date of the employment agreement and ending on the date such Incentive Event Payment is earned.

On August 22, 2020, the Company amended Mr. Burch's employment agreement to provide for an equity bonus upon the closing of this offering, in lieu of cash and in-kind bonuses that were provided for in his original employment agreement, including the cancellation of any payments to be made to Mr. Burch upon the termination of employment or a change in control. 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. Upon the closing of this offering, Mr. Burch will receive non-qualified stock options (the "Options"), equal to 6.0% of the outstanding shares of the Company at the time immediately preceding the closing of this offering. The strike price of the Options will be the pre-money value of the Company divided by the shares outstanding immediately prior to the closing of this offering. A previously paid salary advance of $150,000 will offset the equity bonus at the time the Options are issued. The Options will be exercisable at any time within 10 years of the grant. The Company also owes Mr. Burch accrued salary in the amount of $466,667. Promptly after the closing, the Company will pay the accrued salary in cash and equity in the Company's discretion, except

that the Company shall pay at least $266,667 in cash within 30 days of the closing of this offering. Any equity paid shall be issued using an agreed upon valuation per the terms of the employment agreement. If this offering is not completed by April 1, 2021, then the accrued salary will be payable in cash.

Mr. Burch will resign as President and will be appointed to our board of directors upon completion of the Corporate Conversion.

Employment Agreements with new Executive Officers

On April 5, 2020, we entered into written employment agreements with our current Chief Executive Officer, Greg Duncan, our current Vice President of Finance, Angela Walsh, and our current Vice President of Operations, Ralph Grosswald. Below are written descriptions of those employment agreements.

Greg Duncan Employment Agreement

On April 5, 2020, we entered into an employment agreement with Mr. Duncan setting forth the terms of his employment as our Chief Executive Officer. Pursuant to the agreement, Mr. Duncan is entitled to an annual base salary of $500,000, which amount is subject to annual review by and at the sole discretion of our board of directors or the compensation committee. Mr. Duncan is eligible to receive an annual cash bonus equal to or exceeding 50% of his base salary, provided that he achieves performance targets determined by the board of directors or the compensation committee.

The employment agreement has a term commencing on the date thereof and continuing until terminated (i) upon death of the employee, (ii) upon disability, (iii) for cause, (iv) with good reason or without cause, or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection with his employment; (ii) paid vacation leave; (iii) health benefits; and (iv) a severance payment equal to twelve (12) months of base salary and a prorated portion of the applicable cash bonus upon termination by Mr. Duncan for Good Reason or by the Company without Cause (as defined in the agreement), with restrictive covenants applicable for a corresponding period after termination.

In the event Mr. Duncan is terminated six months prior to, or two years after, a Change of Control (as defined in the agreement) by the Company for any reason other than Cause or by Mr. Duncan for Good Reason, then Mr. Duncan shall be entitled to receive a cash payment equal to 1.5 times his then-current annual base salary, plus 1.5 times his cash bonus for the year in which the termination occurs. Such payment shall be in lieu of the severance payment described above.

Pursuant to the employment agreement, upon the closing of this offering, Mr. Duncan is entitled to receive a grant of stock options equal to 5% of the outstanding shares of common stock outstanding immediately after the closing of the offering at an exercise price equal to the price per share of common stock in the offering. The options will be immediately vested and exercisable and will terminate 10 years after the closing date of the offering.

Angela Walsh Employment Agreement

On April 5, 2020, we entered into an employment agreement with Ms. Walsh setting forth the terms of her employment as our Vice President of Finance. Pursuant to the agreement, Ms. Walsh is entitled to an annual base salary of $195,000, which amount is subject to annual review by and at the sole discretion of our board of directors or the compensation committee. Ms. Walsh is eligible to receive an annual cash bonus equal to or exceeding 20% of her base salary, provided that she achieves performance targets determined by the board of directors or the compensation committee.

The employment agreement has a term commencing on the date thereof and continuing until terminated (i) upon death of the employee, (ii) upon disability, (iii) for cause, (iv) with good reason or without cause, or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection with her employment; (ii) paid vacation leave; (iii) health benefits; and (iv) a severance payment equal to twelve (12) months of base salary and a prorated portion of the applicable cash bonus upon

termination by Ms. Walsh for Good Reason or by the Company without Cause (as defined in the agreement), with restrictive covenants applicable for a corresponding period after termination.

In the event Ms. Walsh is terminated six months prior to or two years after a Change of Control (as defined in the agreement) by the Company for any reason other than Cause or by Ms. Walsh for Good Reason, then Ms. Walsh shall be entitled to receive a cash payment equal to 1.0 times her then-current annual base salary, plus 1.0 times her cash bonus for the year in which the termination occurs. Such payment shall be in lieu of the severance payment described above.

Pursuant to the employment agreement, upon the closing of this offering, Ms. Walsh is entitled to receive a grant of stock options equal to 0.5% of the outstanding shares of common stock outstanding immediately after the closing of the offering at an exercise price equal to the price per share of common stock in the offering. The options will be immediately vested and exercisable and will terminate 10 years after the closing date of the offering.

Ralph Grosswald Employment Agreement

On April 5, 2020, we entered into an employment agreement with Mr. Grosswald setting forth the terms of his employment as our Vice President of Operations. Pursuant to the agreement, Mr. Grosswald is entitled to an annual base salary of $195,000, which amount is subject to annual review by and at the sole discretion of our board of directors or the compensation committee. Mr. Grosswald is eligible to receive an annual cash bonus equal to or exceeding 20% of his base salary, provided that he achieves performance targets determined by the board of directors or the compensation committee.

The employment agreement has a term commencing on the date thereof and continuing until terminated (i) upon death of the employee, (ii) upon disability, (iii) for cause, (iv) with good reason or without cause, or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection with his employment; (ii) paid vacation leave; (iii) health benefits; and (iv) a severance payment equal to twelve (12) months of base salary and a prorated portion of the applicable cash bonus upon termination by Mr. Grosswald for Good Reason or by the Company without Cause (as defined in the agreement), with restrictive covenants applicable for a corresponding period after termination.

In the event Mr. Grosswald is terminated six months prior to or two years after a Change of Control (as defined in the agreement) by the Company for any reason other than Cause or by Mr. Grosswald for Good Reason, then Mr. Grosswald shall be 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. Such payment shall be in lieu of the severance payment described above.

Pursuant to the employment agreement, upon the closing of this offering, Mr. Grosswald is entitled to receive a grant of stock options equal to 0.5% of the outstanding shares of common stock outstanding immediately after the closing of the offering at an exercise price equal to the price per share of common stock in the offering. The options will be immediately vested and exercisable and will terminate 10 years after the closing date of the offering.

R. Michael Gendreau, M.D., Ph.D.

On September 10, 2020, we entered into an employment agreement with Dr. Gendreau setting forth the terms of his employment as our Chief Medical Officer. Pursuant to the agreement, Dr. Gendreau is entitled to an annual base salary of $325,000, which amount is subject to annual review by and at the sole discretion of our board of directors or the compensation committee. Dr. Gendreau is eligible to receive an annual cash bonus equal to or exceeding 35% of his base salary, provided that he achieves performance targets determined by the board of directors or the compensation committee.

The employment agreement has a term commencing fifteen days after we convert to a Delaware Corporation in connection with this offering (the “Commencement Date”) and continuing until terminated (i) upon death of the employee, (ii) upon disability, (iii) for cause, (iv) with good reason or without cause, or (v) voluntarily. The employment agreement also contains, among other things, the following material provisions: (i) reimbursement for all reasonable travel and other out-of-pocket expenses incurred in connection

with his employment; (ii) paid vacation leave; (iii) health benefits; and (iv) a severance payment equal to 25% of his then current annual base salary and a prorated portion of the applicable cash bonus payable over a three month period upon termination by Dr. Gendreau for Good Reason or by the Company without Cause (as defined in the agreement), with restrictive covenants applicable for a corresponding period after termination, and health benefits for a period of 12 months, unless Dr. Gendreau becomes eligible for health benefits under another employer.

In the event Mr. Gendreau is terminated six months prior to or two years after a Change of Control (as defined in the agreement) by the Company for any reason other than Cause or by Mr. Gendreau for Good Reason, then Mr. Gendreau shall be 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. Such payment shall be in lieu of the severance payment described above.

Pursuant to the employment agreement, upon the closing of this offering, Dr. Gendreau is entitled to receive a grant of stock options equal to 0.5% of the outstanding shares of common stock outstanding immediately after the closing of the offering at an exercise price equal to the price per share of common stock in the offering. Thirty-three and 1/3 percent (33.333%) of options shall vest and become exercisable on the first anniversary of the Commencement Date provided Dr. Gendreau continues to be employed at such time. Thereafter, the remaining sixty-six and 2/3 percent (66.667%) of the options shall vest and become exercisable in 24 equal monthly installments (at the end of each successive one-month period) following the first anniversary of the Commencement Date, provided Dr. Gendreau continues to be employed on each vesting date. In the case of a change in control event, the options shall be treated as immediately and full vested. The options terminate 10 years after the Commencement Date.

Director Compensation

Directors who are also our employees do not receive compensation for their service on our board of directors. Our non-employee directors are entitled to receive $2,500 for each board meeting each director attends. In addition, the non-employee directors are entitled to reimbursement of reasonable expenses incurred in connection with their duties as a director.

Scientific Advisory Board Compensation

Historically, our non-employee scientific advisors have received $2,500 for each meeting that each advisor attends.

Limitations of Liability and Indemnification

Our certificate of incorporation, which will become effective upon the completion of the Corporate Conversion, limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our certificate of incorporation, which will become effective upon completion of the Corporate Conversion, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we intend to enter into indemnification agreements with our directors and executive officers prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such executive officer or director for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our executive officers or directors.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, executive officers or persons controlling us, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Equity Compensation Plans

Our 2020 Equity Incentive Plan, or the Plan, provides for grants of stock options and stock awards. The purpose of the Plan is to encourage the participants to contribute materially to the growth of the Company, thereby benefitting the Company's stockholders, and will align the economic interests of the participants with those of the stockholders.

Administration. The Plan is administered by the board of directors or a committee appointed by the board. The board has the sole authority to (i) determine the individuals to whom grants shall be made under the Plan, (ii) determine the type, size and terms of the grants to be made to each such individual, (iii) determine the time when the grants will be made and the duration of any applicable exercise or restriction period, including the criteria for exercisability and the acceleration of exercisability, (iv) amend the terms of any previously issued grant, and (v) deal with any other matters arising under the Plan.

Available shares. The aggregate number of shares of our common stock that may be issued pursuant to awards under the Plan is 812,500 shares. If grants of stock options or stock awards under the Plan are canceled or forfeited, the shares subject to such grants will again be available under the Plan.

If there is any change in the number or kind of shares of our stock outstanding (i) by reason of a stock dividend, spinoff, recapitalization, stock split, or combination or exchange of shares, (ii) by reason of a merger, reorganization or consolidation, (iii) by reason of a reclassification or change in par value, or (iv) by reason of any other extraordinary or unusual event affecting the outstanding stock as a class without the receipt of consideration, or if the value of outstanding shares of our stock is substantially reduced as a result of a spinoff or our payment of an extraordinary dividend or distribution, the maximum number of shares of our stock available for grants under the Plan, the maximum number of shares of our stock that any individual participating in this Plan may be granted in any year, the number of shares covered by outstanding grants, the kind of shares issued under this Plan, and the price per share of such grants shall be appropriately adjusted by the board to reflect any increase or decrease in the number of, or change in the kind or value of, issued shares of our stock to preclude, to the extent practicable, the enlargement or dilution of rights and benefits under such grants; provided, however, that any fractional shares resulting from such adjustment shall be eliminated. Any adjustments determined by the board shall be final, binding and conclusive.

Eligibility for participation. Members of our board of directors, as well as employees of, and consultants and advisors to, us or any of our subsidiaries and affiliates will be eligible to receive awards under the Plan.

Award agreements. Awards granted under the Plan are evidenced by award agreements, which need not be identical, and that provide additional terms, conditions, restrictions or limitations covering the grant of the award, including, without limitation, additional terms providing for the acceleration of exercisability or vesting of awards in the event of a Change in Control (as defined in the Plan) or conditions regarding the participant's employment, as determined by the committee.

Stock options. The board may grant nonqualified stock options to any individuals eligible to participate in the Plan and incentive stock options to purchase shares of our common stock only to eligible employees. The committee will determine: (i) the number of shares of our common stock subject to each option; (ii) the term of each option, which may not exceed ten years, or five years in the case of an incentive stock option granted to a 10.0% or greater stockholder; (iii) the exercise price; (iv) the vesting schedule, if any and (v) the other material terms of each option. No incentive stock option or nonqualified stock option may have an exercise price less than the fair market value of a share of our common stock at the time of grant or, in the case of an incentive stock option granted to a 10.0% or greater stockholder, 110.0% of such share's fair market value. Options will be exercisable at such time or times and subject to such terms and conditions as determined by the committee at the time of grant and the exercisability of such options may be accelerated by the committee.

Stock awards. The board may issue shares of our to an employee, non-employee director or advisor under a stock award, upon such terms as the board deems appropriate. Shares of our stock issued pursuant to stock awards may be issued for cash consideration or for no cash consideration, and subject to restrictions or no restrictions, as determined by the board. The board may establish conditions under which restrictions on stock awards shall lapse over a period of time or according to such other criteria as the board deems appropriate.

Stock Units. The board may grant stock units, which represent rights to receive shares of our common stock at a future date determined in accordance with the applicable award agreement. No monetary payment is required for receipt of stock units or the shares issued in settlement of the award. The board may grant stock units subject to the attainment of one or more performance goals or other conditions. Unless otherwise provided by the board, a participant will forfeit any restricted stock units which have not vested prior to the participant's termination of service.

Stock Appreciation Rights. The board may grant stock appreciation rights ("SARs") either in tandem with a related option or independently of any option. A tandem SAR requires the option holder to elect between the exercise of the underlying option for shares of common stock or the surrender of the option and the exercise of the related stock appreciation right. A tandem SAR is exercisable only at the time and only to the extent that the related stock option is exercisable, while a SAR is exercisable at such times or upon such events and subject to such terms, conditions, performance criteria or restrictions as specified by the board. The exercise price of each stock appreciation right may not be less than the fair market value of a share of our common stock on the date of grant Upon the exercise of any stock appreciation right, the participant is entitled to receive an amount equal to the excess of the fair market value of the underlying shares of common stock as to which the right is exercised over the aggregate exercise price for such shares.

Change in Control. In the event of a Change of Control, the board may take any of the following actions with respect to any or all outstanding grants: the Board may (i) determine that outstanding options shall accelerate and become exercisable, in whole or in part, upon the change of control or upon such other event as the board determines, (ii) determine that the restrictions and conditions on outstanding stock awards shall lapse, in whole or in part, upon the change of control or upon such other event as the board determines, (iii) require that grantees surrender their outstanding options in exchange for a payment by us, in cash or stock as determined by the board, in an amount equal to the amount by which the then fair market value of the shares of our stock subject to the grantee's unexercised options exceeds the exercise price of the options or (iv) after giving grantees an opportunity to exercise their outstanding options, terminate any or all unexercised options at such time as the board deems appropriate. Such surrender or termination shall take place as of the date of the change of control or such other date as the board may specify. The board shall have no obligation to take any of the foregoing actions, and, in the absence of any such actions, outstanding awards shall continue in effect according to their terms (subject to any assumption pursuant to as described in the first sentence of this paragraph).

As used in the Plan, a "Change of Control" shall have deemed to occur if:

- Any "person," as such term is used in sections 13(d) and 14(d) of the Exchange Act becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of our securities representing more than 50% of the voting power of our then outstanding securities; provided that a Change of Control shall not be deemed to occur as a result of (A) a transaction in which we become a subsidiary of another corporation and in which our stockholders, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors, or (B) the acquisition of our securities by a stockholder in a capital-raising transaction; or
- The consummation of (A) a merger or consolidation of us with another corporation where our stockholders, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors, (B) a sale or other disposition of all or substantially all of our assets, or (C) our liquidation or dissolution.

The term "transfer" includes any sale, exchange, assignment, gift, bequest, disposition, mortgage, charge, pledge, encumbrance, grant of a security interest or other arrangement by which possession, legal title or beneficial ownership passes from one person to another, or to the same person in a different capacity, whether or not voluntarily and whether or not for value, and including without limitation any merger or amalgamation and any agreement to effect any of the foregoing.

Stockholder rights. Except for (i) stock awards or (ii) as otherwise provided in the applicable award agreement, a participant will have no rights as a stockholder with respect to shares of our common stock covered by any award until the participant becomes the record holder of such shares.

Amendment and termination. Notwithstanding any other provision of the Plan, our board of directors may at any time amend any or all of the provisions of the Plan.

Transferability. Awards granted under the Plan generally will be nontransferable, other than by will or the laws of descent and distribution, except that the committee may provide for the transferability of nonqualified stock options at the time of grant or thereafter to certain family members.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2018 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 or one percent of the average of our total assets as of December 31, 2019 and 2018, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Loan to Company

On February 20, 2018, Dr. Pridgen provided us with a non-interest-bearing loan of $120,000 to fund short-term operations and cash needs. We repaid the full amount of the loan on March 27, 2018.

Equity Interest Grants

On July 17, 2020 our Board approved the issuance of 0.5% membership interest to Dr. Pridgen in consideration for his services to date.

On August 19, 2020, our Board approved the acceleration of the issuance of a 4.5% membership interest to Dr. Pridgen that was contemplated in the Virios Therapeutics Operating Agreement. The grant of the interest was completed to reduce the dilution applicable to current members and in anticipation of the Corporate Conversion.

Policies and Procedures for Related Person Transactions

Our board of directors intends to adopt a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets as of December 31, 2019 and 2018 and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, giving pro form effect to the Corporate Conversion and the conversion of all outstanding convertible promissory notes, as of December 16, 2020 by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power.

Percentage ownership of our common stock prior to this offering is based on 4,832,494 shares of common stock outstanding as of December 16, 2020, after giving effect to (i) the Corporate Conversion, (ii) the conversion of $3,279,133 principal amount convertible promissory notes plus accrued interest upon the closing of this offering into 425,333 shares of our common stock, and (iii) the issuance of 64,862 shares of our common stock upon this offering as payment for accrued management salaries. Percentage ownership of our common stock after this offering is based on 7,832,494 shares of common stock as of December 16, 2020, after giving pro forma effect to our issuance of 3,000,00 shares of our common stock in this offering.

In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to the exercise of options, warrants or other rights held by such person that are currently exercisable or exercisable within 60 days of December 16, 2020, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 44 Milton Avenue, Alpharetta, GA 30009. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Prior to Offering	After Offering
Robert Buchalter	4,905[1]	*	*
Richard Burch	439,843[2]	8.58%	5.41%
Abel De La Rosa	—	—	—
Greg Duncan	410,154[3]	7.83%	4.98%
David Keefer	7,808[4]	*	*
William L. Pridgen, M.D.	726,493[5]	15.03%	9.27%
John C. Thomas, Jr.	—	—	—
Angela Walsh	40,625[6]	*	*
Richard J. Whitley, M.D.	—	—	—
Robert Young	46,968	*	*
Directors and Officers as a group (8 individuals before offering and 9 individuals upon offering)	1,717,421	30.58%	19.93%
Beneficial Owners of more than 5% of our common stock:			
The University of Alabama[7]	323,347	6.69%	4.13%

* Represents beneficial ownership of less than 1%

(1) Includes (i) 3,103 shares of our common stock that will be issued upon conversion of $25,000 principal amount of our convertible promissory notes plus accrued interest and (ii) 801 shares of common stock issuable upon exercise of warrants exercisable within 60 days of December 16, 2020.

(2) Includes (i) stock options to be issued and fully exercisable upon the closing of this offering to purchase 292,500 shares of common stock and (ii) 24,163 shares of our common stock to be issued as payment of accrued salary upon the closing of this offering.

(3) Includes (i) stock options to be issued and fully exercisable upon the closing of this offering to purchase 406,250 shares of common stock, (ii) 3,103 shares of our common stock that will be issued upon conversion of $25,000 principal amount of our convertible promissory notes plus accrued interest, and (iii) 801 shares of common stock issuable upon exercise of warrants exercisable within 60 days of December 16, 2020.

(4) Includes (i) 6,206 shares of our common stock that will be issued upon conversion of $50,000 principal amount of our convertible promissory notes plus accrued interest and (ii) 1,602 shares of common stock issuable upon exercise of warrants exercisable within 60 days of December 16, 2020. The shares of common stock are held by Ethica Group, LLC for which Mr. Keefer is the managing member.

(5) Includes (i) 3,056 shares of our common stock that will be issued upon conversion of $25,000 principal amount of our convertible promissory notes plus accrued interest, (ii) 801 shares of common stock issuable upon exercise of warrants exercisable within 60 days of December 16, 2020, and (iii) 40,699 shares of common stock to be issued as payment of accrued salary upon closing of this offering.

(6) Includes stock options to be issued and fully exercisable upon the closing of this offering to purchase 40,625 shares of common stock.

(7) Dr. Russell J. Mumper, Vice President for Research and Economic Development may be deemed to have voting and dispositive power over the shares held by The University of Alabama. The mailing address for the University of Alabama is 152 Rose Administration, Box 870104, Tuscaloosa, AL 35487- 0104.

DESCRIPTION OF CAPITAL STOCK

General

The following description summarizes important terms of our capital stock and certain provisions of our certificate of incorporation and bylaws, each of which will be in effect upon the completion of the Corporate Conversion. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect the completion of the Corporate Conversion that will occur immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Following the Corporate Conversion, our authorized capital stock will consist 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 16, 2020, after giving effect to the Corporate Conversion, the conversion of the $4,204,133 principal amount of convertible promissory notes plus accrued interest outstanding as of the date hereof and the equity issuance for payment of accrued management salaries, there were 4,832,494 shares of our common stock, held by approximately 200 stockholders of record. 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. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. 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 that will be in effect upon the consummation of this offering could 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
- 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.

Warrants

In connection with the sale of our outstanding convertible promissory notes we issued to each note holder warrants equal to 25% of the principal amount of such holder's note. Each warrant is exercisable upon the conversion of the convertible promissory notes in connection with this offering and each warrant expires 30 days after such date of conversion of the convertible promissory notes. Upon exercise, the holders of the warrants can purchase shares of common stock at an exercise price of $7.80 per share.

Transfer Agent and Registrar

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

National Securities Exchange Listing

The common stock has been approved for listing on the Nasdaq Capital Market under the symbol "VIRI."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of 7,832,494 shares of common stock, assuming the issuance of 3,000,000 shares of common stock offered by us in this offering and no exercise of options after December 16, 2020. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement. Additionally, the Representatives' Warrants may not be sold, transferred, assigned, pledged, or hypothecated for a 180-day period following the effective date of the registration statement, except to any underwriter and selected dealer participating in the offering and their bona fide officers or partners.

The remaining 4,832,494 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that all of these shares will be subject to the 12-month and 180-day lock-up periods under the lock-up agreements described below. Upon expiration of the lock-up periods, we estimate that approximately 7,832,494 shares will be available for sale in the public market, subject in some cases to applicable limitations under Rule 144.

Lock-Up Agreements

In connection with this offering, we, our officers and directors and the holders of our outstanding capital stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any shares of our common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of the lock-up agreement continuing through the date December 16, 2021 (twelve months after the date of this Prospectus), in the case of our directors and officers, and June 16, 2021 (six months after the date of this Prospectus), in the case of our stockholders, except with the prior written consent of ThinkEquity.

Following the lock-up periods set forth in the agreements described above, and assuming that ThinkEquity does not release any parties from these agreements and that there is no extension of the lock-up period, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in "broker's transactions" or certain "riskless principal transactions" or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 78,325 shares immediately after this offering; or
- the average weekly trading volume in our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on

Form 144 with the Securities and Exchange Commission and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the nine months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from an issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Equity Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our stock plans. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

UNDERWRITING

ThinkEquity, a division of Fordham Financial Management, Inc., is acting as the representative of the underwriters of the offering. We have entered into an underwriting agreement dated December 16, 2020 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock at the initial public offering price, less the underwriting discounts and commissions, as set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Underwriter	Number of Shares
ThinkEquity, a division of Fordham Financial Management, Inc.	3,000,000
Total	3,000,000

The underwriters are committed to purchase all the shares of common stock offered by the Company, other than those covered by the over-allotment option to purchase additional shares of common stock described below. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, the underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the shares offered by us in this prospectus are subject to various representations and warranties and other customary conditions specified in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares of common stock subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase up to an aggregate of 450,000 additional shares of common stock (equal to 15% of the total number of shares of common stock sold in this offering) at the public offering price per share, less underwriting discounts and commissions, solely to cover over-allotments, if any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of common stock in proportion to their respective commitments set forth in the prior table.

Discounts, Commissions and Reimbursement

The representative has advised us that the underwriters propose to offer the shares of common stock to the public at the initial public offering price per share set forth on the cover page of this prospectus. The underwriters may offer shares to securities dealers at that price less a concession of not more than $0.40 per share. After the initial offering to the public, the public offering price and other selling terms may be changed by the representative.

The following table summarizes the underwriting discounts and commissions and proceeds, before expenses, to us assuming both no exercise and full exercise by the underwriters of their over-allotment option:

		Total	
	Per Share	Without Option	With Option
Public offering price	$ 10.00	$30,000,000	$34,500,000
Underwriting discounts and commissions (7%)	$ 0.70	$ 2,100,000	$ 2,415,000
Non-accountable expense allowance (1%)	$ 0.10	$ 300,000	$ 345,000
Proceeds, before expenses, to us	$ 9.20	$27,600,000	$31,740,000

We have agreed to pay an expense deposit of $35,000 to (or on behalf of) the representative, which will be applied against the actual out-of-pocket accountable expenses that will be paid by us to the underwriters in connection with this offering, and will be reimbursed to us to the extent not incurred, of which $35,000 has been paid as of the date hereof.

In addition, we have also agreed to pay the following expenses of the underwriters relating to the offering: (a) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed $15,000 in the aggregate; (b) all filing fees and communication expenses associated with the review of this offering by FINRA; (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriter, including the reasonable fees and expenses of the underwriter's blue sky counsel; (d) $29,500 for the underwriters' use of Ipreo's book-building, prospectus tracking and compliance software for this offering; (e) the costs associated with bound volumes of the public offering materials as well as commemorative mementos and lucite tombstones, (f) the fees and expenses of the representatives' legal counsel incurred in connection with this offering in an amount up to $125,000; (g) $10,000 for data services; and (h) up to $20,000 of the representative's actual accountable road show expenses for the offering.

We estimate the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately $938,333.

Representative Warrants

Upon the closing of this offering, we have agreed to issue to the representative warrants, or the Representative's Warrants, to purchase a number of shares of common stock equal to 5.0% of the total number of shares sold in this public offering. The Representative's Warrants will be exercisable at a per share exercise price equal to 125% of the public offering price per share of common stock sold in this offering. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four year period commencing one year from the effective date of the registration statement related to this offering. The Representative's Warrants also provide for one demand registration right of the shares underlying the Representative's Warrants, and unlimited "piggyback" registration rights with respect to the registration of the shares of common stock underlying the Representative's Warrants and customary antidilution provisions. The demand registration right provided will not be greater than five years from the date of the underwriting agreement related to this offering in compliance with FINRA Rule 5110(f)(2)(G). The piggyback registration right provided will not be greater than seven years from the date of the underwriting agreement related to this offering in compliance with FINRA Rule 5110(f)(2)(G).

The Representative's Warrants and the shares of common stock underlying the Representative's Warrants have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative, or permitted assignees under such rule, may not sell, transfer, assign, pledge, or hypothecate the Representative's Warrants or the securities underlying the Representative's Warrants, nor will the representative engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the Representative's Warrants or the underlying shares for a period of 180 days from the effective date of the registration statement. Additionally, the Representative's Warrants may not be sold

transferred, assigned, pledged or hypothecated for a 180-day period following the effective date of the registration statement except to any underwriter and selected dealer participating in the offering and their bona fide officers or partners. The Representative's Warrants will provide for adjustment in the number and price of the Representative's Warrants and the shares of common stock underlying such Representative's Warrants in the event of recapitalization, merger, stock split or other structural transaction, or a future financing undertaken by us.

Pricing of the Offering

Prior to this offering, there has been no established public market for our common stock. The initial public offering price was determined by negotiations among us and the representative of the underwriters. In addition to prevailing market conditions, among the factors considered in determining the initial public offering price of our common stock were:

- the information included in this prospectus and otherwise available to the representative;
- our historical performance;
- estimates of our business potential and our earnings prospects;
- an assessment of our management;
- and the consideration of the above factors in relation to market valuation of companies in related businesses.

An active trading market for the shares of our common stock may not develop. It is also possible that the shares will not trade in the public market at or above the initial public offering price following the closing of this offering.

Our common stock has been approved for listing on the Nasdaq Capital Market under the trading symbol "VIRI." In order to meet one of the requirements for listing the common stock on Nasdaq, the underwriters have undertaken to sell to a minimum of 300 round lot stockholders.

Right of First Refusal

Until December 16, 2022 (twenty four (24) months from the date of the underwriting agreement) the representative shall have an irrevocable right of first refusal to act as sole investment banker, sole book-runner and/or sole placement agent, at the representative sole discretion, for each and every future public and private equity and debt offerings for the Company, or any successor to or any subsidiary of the Company of any series of $50 million or less during such twenty four (24) month period, including all equity linked financings, on terms customary to the representative. The representative shall have the sole right to determine whether or not any other broker-dealer shall have the right to participate in any such offering and the economic terms of any such participation. In the event the representative decides not to exercise its right of first refusal for any two public capital raising transactions that are consummated offerings of less than $50 million, or fails to consummate any two of such transactions, such period shall be automatically terminated. In the event the Company pursues a public offering of more than $50 million and a broker dealer is engaged to be the investment banker, book-runner, and/or placement agent, then the representative shall be entitled to participate as a joint investment banker, joint book-runner and/or joint placement agent with respect to such offering with a minimum of 50% of the economics and fees in the transaction. The representative will not have more than one opportunity to waive or terminate the right of first refusal in consideration of any payment or fee.

Lock-Up Agreements

The Company, the holders of all outstanding membership interests prior to the Corporate Conversion and each of its directors and officers have agreed or (in the case of such holders of outstanding membership interests) are subject to provisions providing that for a period of (i) six months after the date of this prospectus in the case of directors, officers and holders of membership interests and (ii) three months after the date of this prospectus in the case of the Company, without the prior written consent of the representative, not to directly or indirectly:

- issue (in the case of us), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or

otherwise transfer or dispose of any shares of common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock; or

- in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock; or
- complete any offering of debt securities of the Company, other than entering into a line of credit, term loan arrangement or other debt instrument with a traditional bank; or
- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock, whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members. The representative may agree to allocate a number of securities to underwriters and selling group members for sale to its online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us, and should not be relied upon by investors.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares of common stock or preventing or retarding a decline in the market price of our shares of common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Other Relationships

Certain of the underwriters and their affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they may in the future receive customary fees.

Offer restrictions outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area — Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code Monétaire et Financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 ;and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1; and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to

the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societ — $$ — Aga e la Borsa, "CONSOB" pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no.58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 1197l") as amended ("Qualified Investors"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors"

(as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA") has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or

caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Duane Morris LLP. Certain legal matters will be passed upon for the underwriters by Loeb & Loeb LLP.

EXPERTS

The financial statements of Virios Therapeutics, LLC (formerly Innovative Med Concepts, LLC) (the "Company") as of and for the years ended December 31, 2019 and 2018 have been included in this prospectus in reliance upon the report of Dixon Hughes Goodman LLP, an independent registered public accounting firm, which report is also included in this prospectus, upon the authority of said firm as experts in accounting and auditing. The report of Dixon Hughes Goodman LLP contains an explanatory paragraph regarding substantial doubt about the Company's ability to continue as a going concern.

No expert named in the registration statement of which this prospectus forms a part as having prepared or certified any part thereof (or named as having prepared or certified a report or valuation for use in connection with such registration statement) or counsel named in this prospectus as having given an opinion upon the validity of the securities being offered pursuant to this prospectus or upon other legal matters in connection with the registration or offering of such securities was employed for such purpose on a contingency basis. At the time of such preparation, certification or opinion or at any time thereafter, through the date of effectiveness of such registration statement or that part of such registration statement to which such preparation, certification or opinion relates, no such person had, or is to receive, in connection with the offering, a substantial interest, direct or indirect, in our Company or any of its parents or subsidiaries. Nor was any such person connected with our Company or any of its parents or subsidiaries as a promoter, managing or principal underwriter, voting trustee, director, officer or employee.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. Upon completion of this offering, we will be required to file periodic reports, proxy statements, and other information with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934. Securities and Exchange Commission also maintains an Internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the Securities and Exchange Commission. The address of that site is *www.sec.gov.*

INNOVATIVE MED CONCEPTS, LLC

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Report of Independent Registered Public Accounting Firm

To the Members and Board of Directors of Innovative Med Concepts, LLC

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Innovative Med Concepts, LLC (the "Company") as of December 31, 2019 and 2018, the related statements of operations, members' interest/members' deficit, and cash flows, for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred an accumulated deficit of $17.6 million since inception, has not generated revenue from operations and does not expect to experience positive cash flows from operating activities in the near term. These conditions, along with other matters as set forth in Note 1, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to this matter are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 and in accordance with auditing standards generally accepted in the United States of America. 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. 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
July 23, 2020

INNOVATIVE MED CONCEPTS, LLC

BALANCE SHEETS

December 31	2019	2018
Assets		
Current assets:		
Cash	**$ 309,384**	$ 30,026
Prepaid expenses and other current assets	**6,516**	12,372
Total current assets	**315,900**	42,398
Deferred issuance costs	**—**	23,537
Total assets	**$ 315,900**	$ 65,935
Liabilities and members' deficit		
Current liabilities:		
Accounts payable	**$ 35,421**	$ 145,656
Accrued expenses	**525,445**	174,427
Accrued salaries	**1,060,000**	1,006,250
Total current liabilities	**1,620,866**	1,326,333
Convertible promissory notes, net	**3,637,543**	—
Total liabilities	**5,258,409**	1,326,333
Commitments and contingencies (Note 9)		
Preferred members' interests, non-voting, net	**75,000**	1,283,484
Members' deficit:		
Member's interests, voting	**—**	—
Members' interests, non-voting	**12,601,201**	12,601,201
Accumulated deficit	**(17,618,710)**	(15,145,083)
Total members' deficit	**(5,017,509)**	(2,543,882)
Total liabilities and members' deficit	**$ 315,900**	$ 65,935

The accompanying notes are an integral part of these financial statements.

INNOVATIVE MED CONCEPTS, LLC

STATEMENTS OF OPERATIONS

For the years ended December 31	2019	2018
Revenue	**$ —**	$ —
Research and development expenses	**836,175**	854,109
General and administrative expenses	**1,342,324**	1,107,386
Operating loss	**(2,178,499)**	(1,961,495)
Interest expense, net	**(295,128)**	(152,103)
Other income	**—**	6
Loss before provision for income taxes	**(2,473,627)**	(2,113,592)
Provision for income taxes	**—**	—
Net loss	**$(2,473,627)**	$(2,113,592)
Pro forma information (unaudited):		
Net loss	$(2,473,627)	
Pro forma income tax (expense) benefit	—	
Pro forma net loss	$(2,473,627)	
Pro forma net loss per share – basic and diluted	$ (0.51)	
Weighted average pro forma number of shares outstanding – basic and diluted	4,832,499	

The accompanying notes are an integral part of these financial statements.

INNOVATIVE MED CONCEPTS, LLC

STATEMENTS OF MEMBERS' INTERESTS/MEMBERS' DEFICIT

	Voting Member's Interests	Non-voting Members Interests	Accumulated Deficit	Total Members' Deficit
Balance, December 31, 2017	$ —	$12,601,201	$(13,031,491)	$ (430,290)
Net loss	—	—	(2,113,592)	(2,113,592)
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)**

The accompanying notes are an integral part of these financial statements.

INNOVATIVE MED CONCEPTS, LLC

STATEMENTS OF CASH FLOWS

For the years ended December 31	2019	2018
Cash flows from operating activities		
Net loss	**$(2,473,627)**	$(2,113,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of issuance costs	**62,841**	33,016
Provision for uncollectable receivables	**2,160**	15,489
Changes in operating assets and liabilities:		
(Increase) decrease:		
Prepaid expenses and other current assets	**3,696**	(23,694)
Increase (decrease):		
Accounts payable	**(89,824)**	65,638
Accrued expenses	**348,854**	156,355
Accrued salaries	**53,750**	670,833
Net cash used in operating activities	**(2,092,150)**	(1,195,955)
Cash flows from financing activities		
Proceeds from issuance of convertible promissory notes	**2,430,000**	—
Proceeds from issuance of non-voting preferred members' interests	**—**	1,220,000
Payment of deferred issuance costs	**(58,492)**	(69,532)
Net cash provided by financing activities	**2,371,508**	1,150,468
Net increase (decrease) in cash	**279,358**	(45,487)
Cash, beginning of period	**30,026**	75,513
Cash, end of period	**$ 309,384**	$ 30,026
Supplemental disclosure of non-cash financing transactions:		
Accrued deferred issuance costs	**$ 5,290**	$ 23,537
Conversion of non-voting preferred members' interests to convertible promissory notes	**$ 1,245,000**	$ —
Conversion of investor loan to non-voting preferred members' interests	**$ —**	$ 100,000

The accompanying notes are an integral part of these financial statements.

INNOVATIVE MED CONCEPTS, LLC
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018

1. Organization and Nature of Business

Innovative Med Concepts, LLC (the "Company") is a limited liability company ("LLC") formed under the laws of the State of Alabama on February 28, 2012. The duration of the Company shall be perpetual unless the Company is dissolved by law or otherwise terminated. The Company is a development-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 cyclooxegenase-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.

Going Concern

As of December 31, 2019, the Company had an accumulated deficit of approximately $17.6 million and is expected to incur losses in the future as it continues its development activities. In view of these matters, the ability of the Company to continue as a going concern is dependent upon the Company's ability to generate additional financing. Since its inception, the Company has funded its losses primarily through issuance of members' interests and convertible debt instruments.

The Company intends on financing its future development activities and its working capital needs largely from the issuance of convertible debt and sale of equity securities. The Company's current cash on hand, together with any additional capital to be raised in 2020, is intended to fund continuing operations. The Company will continue to require additional funding to remain a going concern and to fund operations until such time, if ever, the Company becomes profitable. Failure to secure the necessary financing in a timely manner and on favorable terms could have a material adverse effect on the Company's strategy and value and could require the delay of product development and clinical trial plans. As a result, substantial doubt exists regarding the Company's ability to continue as a going concern twelve months from the date the financial statements were available to be issued. The financial statements have been prepared on a going concern basis and do not include adjustments to the amounts recognized or classifications of assets and liabilities should the Company be unable to continue as a going concern.

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 ("US GAAP"). Any reference in these notes to applicable guidance is meant to refer to US 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 financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying disclosures. Due to the uncertainty of factors surrounding the estimates or judgements used in the preparation of the financial statements, actual results could differ from these estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker ("CODM") view the Company's operations and manages its business as a single operating segment, which is the business of developing products to treat diseases associated with a viral triggered abnormal immune response. The Company also considered equity method investments for its segment reporting and determined that the CODM does not regularly review the operating results to evaluate whether to retain the relationship.

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 and totaled $309,384 as of December 31, 2019, which exceeded the federally insured limit of $250,000 by $59,384. There were no accounts that exceeded federally insured limits as of December 31, 2018.

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 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. Upon closing, capitalized costs are recognized into interest expense over the terms of the instruments using the effective interest method. In 2019, the Company recognized $26,325 of interest expense related to the amortization of issuance costs for the convertible promissory notes. In 2019 and 2018, the Company recognized $36,516 and $33,016, respectively, of interest expense related to the amortization of issuance costs for the mezzanine preferred members' interests.

Accrued Salaries

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

Income Taxes

The Company is an Alabama limited liability company that passes through income and losses to its members. As a result, the Company is not subject to any U.S. federal or state income taxes as the related tax consequences are reported by the individual members; accordingly, the accompanying financial statements do not reflect a provision for federal and state income taxes.

A tax position is a position taken in a previously filed tax return or a position expected to be taken in a future tax return 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. Consideration is given to the recognition and measurement of tax positions that meet a "more-likely-than-not" threshold. 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, 2019 and 2018. The Company is not currently under examination by the Internal Revenue Service or by state tax authorities.

Unaudited pro forma tax expense

The Company currently operates as an Alabama LLC. Prior to the effectiveness of the anticipated public offering, the Company will convert from an Alabama LLC to a Delaware corporation pursuant to a

statutory conversion. As a result of the corporate conversion, all of the membership interests held by the existing members of the Company will be converted into shares of common stock. The Company will then be taxed as a corporation and will become subject to U.S. Federal and state income taxes. Accordingly, a pro forma income tax provision has been disclosed as if the Company was a taxable corporation for the year ended December 31, 2019. Pro forma tax expense was computed using an estimated effective rate of 0%, inclusive of applicable U.S. federal and state taxes. The Company is in a net operating loss position for the year ended December 31, 2019 and has assessed a valuation allowance against all of its U.S. net deferred tax assets. As such, no pro forma tax expense was computed for U.S. federal and state income tax purposes.

Pro Forma Net Loss Per Share

Net loss per share ("EPS") is computed in accordance with 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. For the years ended December 31, 2019 and 2018 there were no potentially dilutive shares outstanding.

Unaudited pro forma net loss per share

Pro forma net loss per share has been presented for the most recent period. Pro forma basic and diluted net loss per share was computed by dividing pro forma net loss by the weighted average number of common shares outstanding for the year ended December 31, 2019.

Research and Development

Research and development costs are expensed as incurred and are primarily 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-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.

INNOVATIVE MED CONCEPTS, LLC
NOTES TO FINANCIAL STATEMENTS (continued)
DECEMBER 31, 2019 AND 2018

Recent Accounting Pronouncements Not Yet Adopted

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 is evaluating the impact of the pronouncement on its financial statements and does not expect the adoption of this pronouncement to have a material impact.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

December 31	2019	2018
Prepaid insurance	**$ —**	$ 7,871
Prepaid data room hosting services	**5,731**	4,167
Miscellaneous receivables	**785**	334
Total prepaid expenses and other assets	**$6,516**	$12,372

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. 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	2019	2018
Accrued CRO and CMO costs	**$149,178**	$ 35,228
Accrued interest on preferred members' interests	**188,085**	119,257
Accrued interest on promissory notes	**163,123**	—
Other	**25,059**	19,942
	$525,445	$174,427

6. Convertible Promissory Notes, Net

During 2019, the Company completed and closed its fourth offering (the "Fourth Offering") subscription for the issuance of convertible promissory notes (the "Notes") for convertible preferred non-voting membership interests (the "Convertible Interest"). 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 shall bear interest at 8% per annum, with a maximum of term of 18 months. Any accrued interest shall be paid in cash, and not convert into common non-voting membership interests ("Common

Interests"). The principal portion of the instrument is only payable though 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. During 2019, the Company recognized $163,123 of interest expense related to the Notes.

The Convertible Interests shall convert to Common Interests that results 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 is completed within the 18-month term, the Convertible Interests shall automatically convert into Common Interests at the price of $400,000 per 1% of Common Interests. Regardless of the price per Membership Interest used in the next financing, the Convertible Interests shall convert into Common Interests at a rate no less than 1% per $400,000 of Preferred Interests, placing a cap on the valuation of the Company at $40,000,000 for the purposes of the conversion, even if the next equity raise is higher.

The Company determined the conversion feature did not require bifurcation as the embedded conversion option requires physical cash settlement and does not provide for net settlement. Further, the Company determined that the conversion feature was not in the money at issuance and thereby did not represent a beneficial conversion feature.

In addition, each Convertible Interest includes warrant coverage of 25% of the principal value of the Note, which provide an option to purchase additional Common Interests in cash at the same price as the conversion of the Note. The warrant coverage is only exercisable either on the conversion date, or within 30 days of the conversion date. If not exercised within 30 days of the conversion date, the warrant coverage is 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 are only exercisable at the time of conversion or within 30 days of the conversion of the Convertible Interests, and there are restrictions on transfer, they are considered to be non-detachable and do not require to be accounted for separately from the hybrid instrument.

The Notes are unsecured obligations and do 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.

7. Members' Equity

The Company is authorized to issue two classes of membership interests, voting and non-voting. Dr. William Pridgen, the Founder, holds the only voting membership interest of the Company of 1.0031% as of December 31, 2019 and 2018. There is no value assigned to voting membership interest on the balance sheet as of December 31, 2019 and 2018, as the Founder's membership interest was granted for contributed patents that were not assigned a value under US GAAP.

Non-voting 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 bear 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 accumulates 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. The Company recognized $68,828 and $119,257 of interest expense in 2019 and 2018, respectively, relating to the Preferred Membership Interests.

The Preferred Membership Interests are recorded as mezzanine equity, net of issuance cost, on the balance sheets because they are redeemable upon a change in control. The Company does not believe a change in control is considered probable until it occurs and other contingent events requiring redemption are in control of the issuer.

In 2019, in connection with this Fourth Offering, Preferred Membership Interests 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. Related Parties

The Company uses Tanner & Guin (previously Campbell & Guin), a law firm, for general counsel legal services and for administrative needs in connection with the Company's offerings. Partners of the law firm are non-voting members as well as convertible promissory note holders of the Company. The Company paid the firm $217,129 and $156,421 during 2019 and 2018, respectively, and had accounts payable of $14,150 and $74,052 to the firm as of 2019 and 2018, respectively.

The Company uses Way, Ray, Shelton & Co., an accounting firm, for tax accounting services. A partner of the accounting firm is a non-voting member as well as a convertible promissory note holder of the Company. The Company paid the firm $19,098 and $27,770 during 2019 and 2018, 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 $2,160 and $15,489 during 2019 and 2018, respectively. When the payments were made, the Company recognized a receivable on its balance sheet within other current assets for the total amounts paid. As of December 31, 2019 and 2018, the receivable due from NRP for these payments was $20,061 and $17,901, respectively. However, NRP does not have sufficient cash, or operations to support repayment, since the cash balance of NRP at December 31, 2018 and 2019 was $85 and $0, respectively. Management has determined the collectability of this receivable is not probable and fully reserved the outstanding receivables recognizing a bad debt expense of $2,160 and $15,489 for 2019 and 2018 within general and administrative expense on the statement of operations.

On February 20, 2018, the Company's Chief Executive Officer provided a non-interest-bearing loan of $120,000 to the Company to fund short-term operations and cash needs. The amount was repaid in full on March 27, 2018.

9. Commitments and Contingencies

Litigation and Other

The Company is not aware of any litigation or claims, the outcome of which will materially affect its financial condition or results of operations. Any legal costs incurred in connection with loss contingencies would be expensed as incurred.

Employment Agreement and Deferred Compensation Plan

The Company has an executive employment agreement with the President of the Company, effective as of January 26, 2014. Under the terms of this agreement, the President is entitled to an incentive plan (the "Incentive Plan") whereby a cash or in-kind bonus is payable upon one of the following events: i) the sale or license of a pharmaceutical product, compound, molecule, composition or other property developed by the Company, ii) a sale of all or substantially all the assets of the Company, majority of the membership interests, or majority voting membership interest such that the Company is no longer controlled by Dr. Pridgen, iii) a merger or consolidation of the Company, or iv) the sale, license, or disposition relating to the first indication of fibromyalgia.

The amounts payable to the executive depends upon the total proceeds received, and range from 2.5% – 6.0% of the proceeds that include all upfront and contingent payments, including all milestone payments, prepaid royalties, and other structured payments.

The Company has not recognized any expense or associated liability in connection with the potential cash bonus amounts as they are not considered probable as of December 31, 2019 and 2018.

In addition, if the payable event is the result of the sale, license, or disposition relating to the first indication of fibromyalgia, the executive earns additional non-voting membership interests based upon total proceeds received that ranges between 4.0% – 6.0% of the Company's ownership.

The Company has not recognized any expense in connection with the potential equity issuance as the issuance is considered to be an award with a performance condition that is not probable of being satisfied as of December 31, 2019 and 2018.

Strategic Advisor Engagement

In May 2017, the Company entered into an agreement with Torreya 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, 2019 and 2018.

10. Subsequent Events

Subsequent to year-end, an outbreak of a novel strain of coronavirus (COVID-19) emerged globally. Although it is not possible to reliably estimate the length or severity of the pandemic, it could have an adverse financial impact and result in a delay in the ability to raise sufficient funds, timely complete clinical trials, and other adverse effects.

In March 2020, the Company entered into an engagement letter with ThinkEquity, a division of Fordham Financial Management, Inc., to act as the sole book-runner for the proposed initial public

offering (the "Offering") of common stock of the Company. Upon the successful completion of the Offering, the Company will pay ThinkEquity (or in the event that an underwriting syndicate is created, the underwriters as a group, the "Underwriting Syndicate") an underwriting discount of 7% of the aggregate gross proceeds from the Offering. The Underwriting Syndicate will also be entitled to receive a non-accountable expense allowance equal to 1% of the aggregate gross public proceeds from the Offering. The Company paid an advance of $35,000 upon the execution of the engagement letter which will be applied against actual out-of-pocket accountable expenses. At the closing of the Offering, as additional compensation, ThinkEquity will be issued warrants (the "Underwriter's Warrants") to purchase that number of shares of Common Stock equal to 5% of the aggregate number of shares sold in the Offering. The Underwriter's Warrants will be exercisable at any time and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the Offering, at a price per share equal to 125.0% of the public offering price per share of common stock at the Offering. In addition, the Underwriting Syndicate has the right to acquire up to an additional 15% of total shares offered for the purposes of covering over-allotments.

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 for convertible preferred non-voting membership 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. The Fifth Offering has the same terms and conditions of the Fourth Offering (Note 6) including 25% warrant coverage on the principal of the notes.

Subsequent to year-end, 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 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. In addition to the cash bonus, each Executive, immediately upon the closing of any offering or Company debt or equity securities that results in the Company having sufficient funds to complete the Company's Phase 2b trial (e.g., a minimum total raise of $25 million), and whether such funds are raised through a private or public offering or combination thereof (the "Triggering Offering"), the Company shall issue a 5%, 0.5% and 0.5% non-voting membership interest in the Company to the CEO, VP of Operations and the VP of Finance, respectfully, as a profits interest (the "Equity Bonus"). In the event that the Company converts into a corporation before or simultaneously with the Triggering Offering, instead of issuing the profits interests as described above, each Executive will be issued an option (the "Option") to purchase their respective percentage of the Company's common stock issued and outstanding as of the date of the grant to each Executive, after accounting for dilution of the issuance to each Executive. The options shall be immediately vested and may be exercisable in whole or in part at fair market value. In lieu of the Equity Bonus or Option, in the event of a "Sale Event" as defined below, each Executive shall be paid a bonus equal to their respective percentages above, of the gross amount of cash, cash-like items, and publicly tradable stock received by the Company or its Members from the Sale Event. A Sale Event shall mean i) the sale or license of a pharmaceutical product, compound, molecule, composition or other property developed by the Company, ii) a sale of all or substantially all the assets of the Company or majority of the membership interests, or iii) a merger or consolidation of the Company. 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 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.

Effective May 14, 2020 the Company terminated its agreement with Torreya, however, the termination does not affect the Company's obligations to pay any fees related to a transaction fee or strategic transaction fee as discussed above for a period of twelve (12) months after the effective date of termination.

In May 2020, the Manager of NRP who is the Company CEO and Founder, issued a letter to all the members of NRP stating that 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, $15,120, by way of reduction in the amounted owed to him by the Company. The remaining 25% will be deemed a capital contribution to NRP by the Company to maintain its 25% ownership in NRP.

On July 1, 2020, the Company's Board approved the opening of the third round of the Fifth Offering to raise up to $2,129,867 of convertible promissory notes.

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 initial public offering ("IPO"), if and when it is completed, the Company will pay the accrued salary in cash or equity, in its discretion. Any cash portion must be paid within 30 days of the IPO. Any equity portion will be issued using an agreed upon valuation per the agreement and shall be considered issued immediately before the IPO. A salary advance of $100,000 paid to Dr. Pridgen in 2014 and 2015, will be offset against the cash portion or the equity portion at the option of Dr. Pridgen. If the Company does not complete the IPO and raises funds privately, then the accrued salary will be repaid when the Board deems there is sufficient cash to do so under the original terms of the Company's operating agreement.

On July 17, 2020 the Company's Board approved, among other things, the change of the Company's name to Virios Therapeutics, LLC, the conversion of the Company to a Delaware corporation upon effectiveness of the Company's registration statement, adoption of the 2020 Equity Incentive Plan whereby 10% of the outstanding stock is reserved for issuance, to be effective upon the closing of the IPO, and an issuance of 0.5% membership interest to Dr. Pridgen.

On July 21, 2020, the Company amended the President's executive employment agreement (the "Employment Agreement") to provide for an equity bonus and a separate cash bonus upon the completion of the IPO, in lieu of other bonuses that were provided for in the Employment Agreement. In the event the Company completes an IPO where proceeds are used exclusively to fund clinical trials or other operating and development expenses ("Financing IPO"), the President will receive restricted stock units ("RSUs") equal to 5.0% of the outstanding shares of the Company immediately preceding the IPO in lieu of the cash bonus and equity bonus discussed in Note 9 above. The strike price of the RSUs will be the pre-money value of the Company divided by the shares outstanding immediately prior to the closing of the IPO. The pre-money value of the Company is the aggregate value of the public company stock issued to the Company's pre-existing investors at the time of the IPO (i.e., those investors who receive publicly traded stock in exchange for membership interests in the Company already owned before the IPO). The RSUs will be exercisable at any time within 10 years of the grant. In addition, upon completion of the IPO, the President will receive a cash bonus equal to 1.0% of the pre-money value of the Company to be paid within 30 days of closing the IPO. If a Financing IPO is not completed on or before April 1, 2021, then the bonuses related to the IPO will no longer apply and will be null and void. The Company also owes the President accrued salary in the amount of $466,667. Promptly after the earlier of the closing of any Incentive Event (Note 9) or Financing IPO, the Company will pay the accrued salary in cash and equity in the Company's discretion, except that the Company shall pay at least $266,667 in cash within 30 days of the event. Any equity paid shall be issued using an agreed upon valuation per the terms of the Employment Agreement. A previously paid salary advance of $150,000 will be offset against the cash bonus portion. If neither an Incentive Event or Financing IPO has been completed by April 1, 2021 then the accrued salary will be payable in cash.

Virios Therapeutics, LLC

Balance Sheets

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash	**$ 499,082**	$ 309,384
Prepaid expenses and other current assets	**61,014**	6,516
Total current assets	**560,096**	315,900
Deferred issuance costs	**225,278**	—
Total assets	**$ 785,374**	$ 315,900
Liabilities and members' deficit		
Current liabilities:		
Accounts payable	**$ 199,366**	$ 35,421
Accrued expenses	**569,395**	525,445
Accrued salaries	**1,015,713**	1,060,000
Total current liabilities	**1,784,474**	1,620,866
Convertible promissory notes, net	**4,150,776**	3,637,543
Total liabilities	**5,935,250**	5,258,409
Commitments and contingencies (Note 9)		
Preferred members' interests, non-voting, net	**75,000**	75,000
Members' deficit:		
Members' interests, voting	**16,239,001**	—
Members' interests, non-voting	**—**	12,601,201
Accumulated deficit	**(21,463,877)**	(17,618,710)
Total members' deficit	**(5,224,876)**	(5,017,509)
Total liabilities and members' deficit	**$ 785,374**	$ 315,900

See accompanying notes to unaudited financial statements.

Virios Therapeutics, LLC

Statements of Operations
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30, 2020	**September 30, 2019**	**September 30, 2020**	**September 30, 2019**
Revenue	**$ —**	$ —	**$ —**	$ —
Research and development expenses	**108,086**	392,832	**161,944**	541,073
General and administrative expenses	**2,554,724**	343,496	**3,421,798**	1,071,696
Operating loss	**(2,662,810)**	(736,328)	**(3,583,742)**	(1,612,769)
Interest expense, net	**(104,440)**	(75,491)	**(304,646)**	(222,269)
Other income	**43,221**	—	**43,221**	—
Loss before provision for income taxes	**(2,724,029)**	(811,819)	**(3,845,167)**	(1,835,038)
Provision for income taxes	**—**	—	**—**	—
Net loss	**$ (2,724,029)**	$ (811,819)	**$ (3,845,167)**	$ (1,835,038)
Pro forma information (unaudited):				
Loss before taxes	**$ (2,724,029)**		**$ (3,845,167)**	
Pro forma tax expense	**—**		**—**	
Pro forma net loss	**$ (2,724,029)**		**$ (3,845,167)**	
Pro forma net loss per share – basic and diluted	**$ (0.56)**		**$ (0.80)**	
Weighted average pro forma number of shares outstanding – basic and diluted	**4,832,494**		**4,832,494**	

See accompanying notes to unaudited financial statements.

Virios Therapeutics, LLC

Statements of Members' Interests/Members' Deficit (Unaudited)

	Voting Member's Interests	Non-voting Members' Interests	Accumulated Deficit	Total Members' Deficit
Balance, December 31, 2018	$ —	$ 12,601,201	$ (15,145,083)	$ (2,543,882)
Net loss	—	—	(455,363)	(455,363)
Balance, March 31, 2019	—	12,601,201	(15,600,446)	(2,999,245)
Net loss	—	—	(567,856)	(567,856)
Balance, June 30, 2019	—	12,601,201	(16,168,302)	(3,567,101)
Net loss	—	—	(811,819)	(811,819)
Balance, September 30, 2019	**$ —**	**$ 12,601,201**	**$ (16,980,121)**	**$ (4,378,920)**

	Voting Members' Interests	Non-voting Members' Interests	Accumulated Deficit	Total Members' Deficit
Balance, December 31, 2019	$ —	$ 12,601,201	$ (17,618,710)	$ (5,017,509)
Net loss	—	—	(466,553)	(466,553)
Balance, March 31, 2020	—	12,601,201	(18,085,263)	(5,484,062)
Membership conversion to voting interests	12,601,201	(12,601,201)	—	—
Net loss	—	—	(654,585)	(654,585)
Balance, June 30, 2020	**$12,601,201**	**$ —**	**$ (18,739,848)**	**$ (6,138,647)**
Conversion of convertible promissory notes	1,637,800	—	—	1,637,800
Equity-based compensation expense	2,000,000	—	—	2,000,000
Net loss	—	—	(2,724,029)	(2,724,029)
Balance, September 30, 2020	**$16,239,001**	**$ —**	**$ (21,463,877)**	**$ (5,224,876)**

See accompanying notes to unaudited financial statements.

Virios Therapeutics, LLC

Statements of Cash Flows
(Unaudited)

For the nine months ended September 30	2020	2019
Cash flows from operating activities		
Net loss	**$(3,845,167)**	$(1,835,038)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of issuance costs	**42,071**	50,894
(Recovery) provision for uncollectable receivables	**(15,020)**	1,967
Equity-based compensation	**2,000,000**	—
Changes in operating assets and liabilities:		
(Increase) decrease:		
Prepaid expenses and other current assets	**(39,478)**	1,294
Increase (decrease):		
Accounts payable	**156,139**	(74,253)
Accrued expenses	**136,908**	210,117
Accrued salaries	**(44,287)**	24,583
Net cash used in operating activities	**(1,608,834)**	(1,620,436)
Cash flows from financing activities		
Proceeds from issuance of converibile promissory notes	**1,994,133**	1,850,000
Payment of deferred issuance costs	**(57,971)**	(52,922)
Payment of proposed public offering costs	**(137,630)**	—
Net cash provided by financing activities	**1,798,532**	1,797,078
Net increase in cash	**189,698**	176,642
Cash, beginning of period	**309,384**	30,026
Cash, end of period	**$ 499,082**	$ 206,668
Supplemental cash flow disclosures:		
Cash paid for interest	**$ 3,000**	**$ —**
Non-cash financing transactions:		
Deferred public offering costs included in accounts payable	**$ 7,806**	**$ —**
Deferred public offering costs included in accrued expenses	**$ 79,842**	**$ —**
Deferred issuance costs included in accounts payable	**$ —**	$ 6,802
Conversion of convertible promissory notes and accrued interest into membership interests	**$ 1,637,800**	$ —
Conversion of non-voting preferred members' interests to convertible promissory notes	**$ —**	$ 540,000

See accompanying notes to unaudited financial statements.

Virios Therapeutics, LLC

Notes to Unaudited Interim Financial Statements

1 Organization and Nature of Business

Virios Therapeutics, LLC a.k.a. Innovative Med Concepts, LLC (the "Company") is a limited liability company ("LLC") formed 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 duration of the Company shall be perpetual unless the Company is dissolved by law or otherwise terminated. The Company is 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"). The Company is developing its initial development candidate, IMC-1, for people who are suffering from FM. Research has shown that Herpes Simplex Virus-1 ("HSV-1") could be a potential 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 cyclooxegenase-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.

Going Concern

As of September 30, 2020, the Company had an accumulated deficit of approximately $21.5 million and is expected to incur losses in the future as it continues its development activities. In view of these matters, the ability of the Company to continue as a going concern is dependent upon the Company's ability to generate additional financing. Since its inception, the Company has funded its losses primarily through issuance of members' interests and convertible debt instruments.

The Company intends on financing its future development activities and its working capital needs largely from the issuance of convertible debt and sale of equity securities. The Company's current cash on hand, together with any additional capital to be raised in 2020, is intended to fund continuing operations. The Company will continue to require additional funding to remain a going concern and to fund operations until such time, if ever, the Company becomes profitable. Failure to secure the necessary financing in a timely manner and on favorable terms could have a material adverse effect on the Company's strategy and value and could require the delay of product development and clinical trial plans.

The Coronavirus ("COVID-19") pandemic has negatively impacted, and may continue to impact, the macroeconomic environment in the United States and globally. Although it is not possible to reliably estimate the length or severity of the pandemic, it could have an adverse financial impact and result in a delay in the ability to raise sufficient funds, timely complete clinical trials, and other adverse effects. As a result, substantial doubt exists regarding the Company's ability to continue as a going concern twelve months from the date the financial statements were available to be issued. The financial statements have been prepared on a going concern basis and do not include adjustments to the amounts recognized or classifications of assets and liabilities should the Company be unable to continue as a going concern.

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 ("US GAAP"). Any reference in these notes to applicable guidance is meant to refer to US 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 financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying disclosures. Due to the uncertainty of factors surrounding the estimates or judgements used in the preparation of the financial statements, actual results could differ from these estimates.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company chief operating decision-maker ("CODM") view the Company's operations and manage the business as a single operating segment, which is the business of developing products to treat diseases associated with a viral triggered abnormal immune response. The Company also considered equity method investments for its segment reporting and determined that the CODM does not regularly review the operating results to evaluate whether to retain the relationship.

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 and totaled $499,082 and $309,384 as of September 30, 2020 and December 31, 2019, respectively, which exceeded the federally insured limit of $250,000.

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 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. Upon closing, capitalized costs 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:

	Three Months Ended		Nine Months Ended	
	September 30, 2020	**September 30, 2019**	**September 30, 2020**	**September 30, 2019**
Convertible promissory notes	**$ 14,749**	$ 7,559	**$ 42,071**	$ 17,650
Mezzanine preferred members' interests	—	4,764	—	33,244
	$ 14,749	$ 12,323	**$ 42,071**	$ 50,894

Accrued Salaries

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

Income Taxes

The Company is an Alabama limited liability company that passes through income and losses to its members. As a result, the Company is not subject to any U.S. federal or state income taxes as the related tax consequences are reported by the individual members; accordingly, the accompanying financial statements do not reflect a provision for federal and state income taxes.

A tax position is a position taken in a previously filed tax return or a position expected to be taken in a future tax return 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. Consideration is given to the recognition and measurement of tax positions that meet a "more-likely-than-not" threshold. 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 September 30, 2020 and December 31, 2019. The Company is not currently under examination by the Internal Revenue Service or by state tax authorities.

Unaudited pro forma tax expense

The Company currently operates as an Alabama LLC. Prior to the effectiveness of the anticipated public offering, the Company will convert from an Alabama LLC to a Delaware corporation pursuant to a statutory conversion. As a result of the corporate conversion, all of the membership interests held by the existing members of the Company will be converted into shares of common stock. The Company will then be taxed as a corporation and will become subject to U.S. Federal and state income taxes. Accordingly, a pro forma income tax provision has been disclosed as if the Company was a taxable corporation for the nine months ended September 30, 2020. Pro forma tax expense was computed using an estimated effective rate of 0%, inclusive of applicable U.S. federal and state taxes. The Company is in a net operating loss position for the three and nine months ended September 30, 2020 and has assessed a valuation allowance against all of its U.S. net deferred tax assets. As such, no pro forma tax expense was computed for U.S. federal and state income tax purposes.

Pro Forma Net Loss Per Share

Net loss per share ("EPS") is computed in accordance with 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. For the nine months ended September 30, 2020 and 2019 there were no potentially dilutive shares outstanding.

Unaudited pro forma net loss per share

Pro forma net loss per share has been presented for the most recent period. Pro forma basic and diluted net loss per share was computed by dividing pro forma net loss by the weighted average number of common shares outstanding for the nine months ended September 30, 2020.

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-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.

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU 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 is evaluating the impact of the pronouncement on its financial statements and does not expect the adoption of this pronouncement to have a material impact.

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, 2021, 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 $5,744 and $21,534 for the three and nine months ended September 30, 2019, respectively.

3 Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2020	December 31, 2019
Prepaid insurance	**$ 4,347**	$ —
Prepaid legal fees	**50,000**	—
Prepaid services	**6,667**	5,731
Miscellaneous receivables	**—**	785
Total prepaid expenses and other assets	**$ 61,014**	$ 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. The Agreement is in effect for 25 years and will terminate on June 1, 2037.

5 Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2020	December 31, 2019
Accrued CRO and CMO costs	**$ —**	$ 149,178
Accrued interest on preferred members' interests	**188,085**	188,085
Accrued interest on promissory notes	**249,657**	163,123
Accrued public offering costs	**79,842**	
Accrued vacation	**34,654**	—
Other	**17,157**	25,059
	$ 569,395	$ 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 are substantially identical to those of the Third Round, except that the Third Round allows 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 is considered to be on a*pari passu* basis with the Fourth Offering, discussed below, such that all subscriptions received shall be 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 shall bear 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 will convert into common membership interests ("Common Interests"), otherwise the accrued interest will be paid in cash. The principal portion of the instrument is only payable though 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:

	Three Months Ended		Six Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Fourth offering	**$ 50,940**	$ 48,061	**$ 197,324**	$ 106,322
Fifth offering	**38,750**	—	**65,010**	—
	$ 89,690	$ 48,061	**$ 262,334**	$ 106,322

The Convertible Interests shall convert to Common Interests that results 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 is completed within the 18-month term, the Convertible Interests shall automatically convert into Common Interests at the price of $400,000 per 1% of Common Interests. Regardless of the price per Membership Interest used in the next financing, the Convertible Interests shall convert into Common Interests at a rate no less than 1% per $400,000 of Preferred Interests, placing a cap on the valuation of the Company at $40,000,000 for the purposes of the conversion, even if the next equity raise is higher.

The Company determined the conversion feature of the Notes do not require bifurcation as the embedded conversion option requires physical cash settlement and does not provide for net settlement. Further, the Company determined that the conversion feature of the Notes was not in the money at issuance and thereby did not represent a beneficial conversion feature.

In addition, each Convertible Interest includes warrant coverage of 25% of the principal value of the Note, which provide an option to purchase additional Common Interests in cash at the same price as the conversion of the Note. The warrant coverage is only exercisable either on the conversion date, or within 30 days of the conversion date. If not exercised within 30 days of the conversion date, the warrant coverage is 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 are only exercisable at the time of conversion or within 30 days of the conversion of the Convertible Interests, and there are restrictions on transfer, they are considered to be non-detachable and do not require to be accounted for separately from the hybrid instrument.

The Notes are unsecured obligations and do 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.

7 Members' Equity

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, at September 30, 2020, 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 US 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. As the Company contemplates the conversion to a Delaware corporation upon effectiveness of the Company's registration statement, 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 three and nine months ended September 30, 2020, the Company recognized $2,000,000 of compensation expense for these issuances.

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.

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 bear 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 accumulates 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 three months and nine months ended September 30, 2020. The Company recognized $15,106 and $64,717 of interest expense for the three months and nine months ended September 30, 2019, respectively, relating to the Preferred Membership Interests.

The Preferred Membership Interests are recorded as mezzanine equity, net of issuance cost, on the balance sheets because they are redeemable upon a change in control. The Company does not believe a change in control is considered probable until it occurs and other contingent events requiring redemption are in control of the issuer.

In 2019, in connection with this Fourth Offering, Preferred Membership Interests 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 Related Parties

The Company uses Tanner & Guin (previously Campbell & Guin), a law firm, for general counsel legal services and for administrative needs in connection with the Company's offerings. Partners of the law firm members as well as convertible promissory note holders of the Company. The Company paid the firm $132,233

and $316,511 during the three and nine months ended September 30, 2020, respectively, and $45,727 and $190,382 during the three and nine months ended September 30, 2019, respectively. In addition, the Company had accounts payable of $33,040 and $14,150 to the firm as of September 30, 2020 and December 31, 2019, respectively.

The Company uses Way, Ray, Shelton & Co., an accounting firm, for tax accounting services. A retired partner of the accounting firm is a member as well as a convertible promissory note holder of the Company. The Company paid the firm $0 and $22,110 during the three and nine months ended September 30, 2020, respectively, and $0 and $19,098 during the three and nine months ended September 30, 2019, respectively. In addition, the Company had an accrued liability of $12,826 to the firm as of September 30,2020 and none as of September 30, 2019.

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 $0 and $100 during the three and nine months ended September 30, 2020, respectively, and $0 and $1,967 during the three and nine months ended September 30, 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 three and nine months ended September 30, 2020, the Company recognized a net recovery of bad debt expense in the amount of $0 and $15,020, respectively. For the three and nine months ended September 30, 2019, the Company recognized bad debt expense in the amount of $0 and $1,967, respectively. The receivable due from NRP was $0 and $20,061 as of September 30, 2020 and December 31, 2019, respectively.

9 Commitments and Contingencies

Litigation and Other

The Company is not aware of any litigation or claims, the outcome of which will materially affect its financial condition or results of operations. Any legal costs incurred in connection with loss contingencies would be expensed as incurred.

2020 Equity Incentive Plan

The Company's Board and members approved the 2020 Equity Incentive Plan (the "Plan') which is an equity-based incentive plan, the adoption of which is contingent upon the effectiveness of the Company's registration statement. The Plan provides for grants of stock options and awards. The aggregate number of available shares to be issued under the Plan will be equal to 10% of the outstanding shares after the initial public offering ("IPO") and is estimated to be approximately 812,500 shares.

Employment Agreement and Deferred Compensation Plan

The Company has an executive employment agreement with the President of the Company, effective as of January 26, 2014. Under the terms of this agreement, the President is entitled to an incentive plan (the "Incentive Plan") whereby a cash or in-kind bonus is payable upon one of the following events: i) the sale or license of a pharmaceutical product, compound, molecule, composition or other property developed by the Company, ii) a sale of all or substantially all the assets of the Company, majority of the membership interests, or majority voting membership interest such that the Company is no longer controlled by Dr. Pridgen, iii) a merger or consolidation of the Company, or iv) the sale, license, or disposition relating to the first indication of fibromyalgia.

The amounts payable to the executive depend upon the total proceeds received and range from 2.5% – 6.0% of the proceeds that include all upfront and contingent payments, including all milestone payments, prepaid royalties, and other structured payments.

The Company has not recognized any expense or associated liability in connection with the potential cash bonus amounts as they are not considered probable as of September 30, 2020 and December 31, 2019.

In addition, if the payable event is the result of the sale, license, or disposition relating to the first indication of fibromyalgia, the executive earns additional membership interests based upon total proceeds received that range between 4.0% – 6.0% of the Company's ownership. These membership interests are granted after the cash bonuses are paid to allow for any future company appreciation.

The Company has not recognized any expense in connection with the potential equity issuance as the issuance is considered to be an award with a performance condition that is not probable of being satisfied as of September 30, 2020 and December 31, 2019.

On August 22, 2020, the Company amended the President's executive employment agreement to provide for an equity bonus 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. In the event the Company completes an IPO where proceeds are used exclusively to fund clinical trials or other operating and development expenses ("Financing IPO"), the President will receive non-qualified stock options (the "Options") equal to 6.0% of the outstanding shares of the Company immediately preceding the IPO. The strike price of the Options will be the pre-money value of the Company divided by the shares outstanding immediately prior to the closing of the IPO. The pre-money value of the Company is the aggregate value of the public company stock issued to the Company's pre-existing investors at the time of the IPO (i.e., those investors who receive publicly traded stock in exchange for membership interests in the Company already owned before the IPO). A previously paid bonus advance of $150,000 will offset the equity bonus at the time the Options are issued. The Options will be exercisable at any time within 10 years of the grant. If a Financing IPO is not completed on or before April 1, 2021, then the equity bonus related to the IPO will no longer apply and will be null and void and the original bonuses under the President's original contract will remain. The Company also owes the President accrued salary in the amount of $466,667. Promptly after the earlier of the closing of any Incentive Event (discussed above) or Financing IPO, the Company will pay the accrued salary in cash and equity in the Company's discretion, except that the Company shall pay at least $266,667 in cash within 30 days of the event. Any equity paid shall be issued using an agreed upon valuation per the terms of the Employment Agreement. If neither an Incentive Event or Financing IPO has been completed by April 1, 2021 then the accrued salary will be payable in cash.

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 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. In addition to the cash bonus, each Executive, immediately upon the closing of any offering or Company debt or equity securities that results in the Company having sufficient funds to complete the Company's Phase 2b trial (e.g., a minimum total raise of $25 million), and whether such funds are raised through a private or public offering or combination thereof (the "Triggering Offering"), the Company shall issue a 5%, 0.5% and 0.5% membership interest in the Company to the CEO, VP of Operations and the VP of Finance, respectfully, as a profits interest (the "Equity Bonus"). In the event that the Company converts into a corporation before or simultaneously with the Triggering Offering, instead of issuing the profits interests as described above, each Executive will be issued an option (the "Option") to purchase their respective percentage of the Company's common stock issued and outstanding as of the date of the grant to each Executive, after accounting for dilution of the issuance to each Executive. The options shall be immediately vested and may be exercisable in whole or in part at fair market value. In lieu of the Equity Bonus or Option, in the event of a "Sale Event" as defined below, each Executive shall be paid a bonus equal to their respective percentages above, of the gross amount of cash, cash-like items, and publicly tradable stock received by the Company or its Members from the Sale Event. A Sale Event shall mean i) the sale or

license of a pharmaceutical product, compound, molecule, composition or other property developed by the Company, ii) a sale of all or substantially all the assets of the Company or majority of the membership interests, or iii) a merger or consolidation of the Company. 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 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, if and when it is completed, the Company will pay the accrued salary in cash or equity, in its discretion. Any cash portion must be paid within 30 days of the IPO. Any equity portion will be issued using an agreed upon valuation per the agreement and shall be considered issued immediately before the IPO. A salary advance of $100,000 paid to Dr. Pridgen in 2014 and 2015, will be offset against the cash portion or the equity portion at the option of Dr. Pridgen. If the Company does not complete the IPO and raises funds privately, then the accrued salary will be repaid when the Board deems there is sufficient cash to do so under the original terms of the Company's operating agreement.

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 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 an option (the "Option") to purchase 0.5% of the number of shares of the Company's common stock issued and outstanding as of the date of grant at a fair market value equal to the trading value of one share of the Company's common stock at the close of trading on the Commencement Date. No portion of the option may be exercised until such portion shall have vested and become exercisable. Provided that Dr. Gendreau continues to be employed by the Company, the vesting of the Option will be thirty-three and 1/3 percent (33.333%) of the shares will vest and become exercisable on the first anniversary of the Commencement Date. Thereafter, the remaining sixty-six and 2/3 percent (66.667%) of the shares will vest and become exercisable in 24 equal monthly installments following the first anniversary of the Commencement Date. In the event of a change in control, the Option and shares shall be treated as immediately and fully vested. The Option terminates 10 years after the Commencement Date. 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.

Strategic Advisor Engagement

In May 2017, the Company entered into an agreement with Torreya 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.

Effective May 14, 2020 the Company terminated its agreement with Torreya, however, the termination does not affect the Company's obligations to pay any fees related to a transaction fee or strategic transaction fee as discussed above for a period of twelve (12) months after the effective date of termination.

Underwriter Engagement

In March 2020, the Company entered into an engagement letter with ThinkEquity, a division of Fordham Financial Management, Inc., to act as the sole book-runner for the proposed IPO (the "Offering") of common stock of the Company. Upon the successful completion of the Offering, the Company will pay ThinkEquity (or in the event that an underwriting syndicate is created, the underwriters as a group, the "Underwriting Syndicate") an underwriting discount of 7% of the aggregate gross proceeds from the Offering. The Underwriting Syndicate will also be entitled to receive a non-accountable expense allowance equal to 1% of the aggregate gross public proceeds from the Offering. The Company paid an advance of $35,000 upon the execution of the engagement letter which will be applied against actual out-of-pocket accountable expenses. At the closing of the Offering, as additional compensation, ThinkEquity will be issued warrants (the "Underwriter's Warrants) to purchase that number of shares of Common Stock equal to 5% of the aggregate number of shares sold in the Offering. The Underwriter's Warrants will be exercisable at any time and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the Offering, at a price per share equal to 125.0% of the public offering price per share of common stock at the Offering. In addition, the Underwriting Syndicate has the right to acquire up to an additional 15% of total shares offered for the purposes of covering over-allotments.

3,000,000 Shares of Common Stock

Virios Therapeutics, Inc.

PROSPECTUS

ThinkEquity
a division of Fordham Financial Management, Inc.

December 16, 2020

Through and including January 10, 2021 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.