**PART II**

**OFFERING MEMORANDUM DATED May 25, 2021**

SafeRx Pharmaceuticals Inc.
PO Box #2102, Lenox, MA 01240
https://saferxpharmaceuticals.com/

Up to $5,000,000 of Class B Non-Voting Common Stock

SafeRx Pharmaceuticals Inc. ("SafeRx," "the company," "we," or "us"), is offering up to $5,000,000 worth of Class B Non-Voting Common Stock. The minimum target amount under this Regulation CF offering is $25,000 (the "Target Amount"). The company must reach its Target Amount of $25,000 by April 30, 2022. Unless the company raises at least the Target Amount of $25,000 under the Regulation CF offering by April 30, 2022, no securities will be sold in this offering, investment commitments will be cancelled, and committed funds will be returned.

**A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.**

**In making an investment decision, investors must rely on their own examination of the issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.**

**The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.**

**These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.**

**This disclosure document contains forward-looking statements and information relating to, among other things, the company, its business plan and strategy, and its industry. These forward-looking statements are based on the beliefs of, assumptions made by, and information currently available to the company's management. When used in this disclosure document and the company offering materials, the words "estimate", "project", "believe", "anticipate", "intend", "expect", and similar expressions are intended to identify forward-looking statements. These statements reflect management's current views with respect to future events and are subject to risks and uncertainties that could cause the company's action results to differ materially from those**

**contained in the forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements to reflect events or circumstances after such state or to reflect the occurrence of unanticipated events.**

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## THE COMPANY AND ITS BUSINESS

### OVERVIEW

SafeRx Pharmaceuticals (the "company" or "SafeRx") is an early-stage pharmaceutical company originally formed as a Delaware Limited Liability Company on June 22, 2020, and converted to a Delaware Corporation on May 10, 2021. SafeRx is in the process of developing a new class of medications called alcohol-resistant opioids ("AROs"). AROs are proprietary, fixed dose combination medications that combine opioids with a medication that deters concurrent alcohol consumption, with the goal of enhancing the safety of prescription opioids.

#### Problem to be Solved

In 2017, the US declared the opioid crisis a National Public Health Emergency and called for additional safety measures. A critical yet previously unaddressed dimension of this crisis involves the combination of opioid pain medications with alcohol, because when taken together these substances interact in the body in a hazardous manner, increasing the risk of overdose and other adverse events dramatically.

According to data from the Centers for Disease Control and Prevention ("CDC"), more than 22% of fatal prescription opioid overdoses are related to concurrent alcohol use[1], and opioid patients with a history of alcohol problems are five times more likely to experience overdose[2-5]. Despite unequivocal recommendations from health authorities for opioid users to abstain from concurrent alcohol consumption, studies have found that between one-third and three-quarters of long-term opioid patients admit to drinking with their medication [2-5]. Yet physicians currently have no effective means of preventing this dangerous behavior in patients with a definitive medical need for opioid therapy.

#### Investment Highlights

- Research suggests a major unmet medical need exists for opioid formulations which prevent concurrent alcohol consumption.
- No FDA-approved opioid products that deter concurrent alcohol consumption currently exist.
- ARO products have the potential to substantially increase the safety of prescription opioids by discouraging the concurrent consumption of alcohol.
- The company has developed a strong patent portfolio (protected through January 2037) and product pipeline.
- Because AROs combine previously approved active pharmaceutical ingredients, SafeRx plans to leverage an abbreviated regulatory pathway that could lead to FDA approval in as little as 2-3 years.

#### How It Works

When taken together, alcohol and opioids interact in the body to produce an exponential degree of central nervous system depression (known as a synergistic reaction), which dramatically increases the risk of overdose[6]

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[1] Jones, C., L. Paulozzi & K. Mack (2014) Alcohol Involvement in Opioid Pain Reliever and Benzodiazepine Drug Abuse-related Emergency Department Visits and Drug-related Deaths- United States 2010. *Morbidity and Mortality Weekly Report*, 63, 881-885.

[2] Landsman-Blumberg, P., N. Katz, K. Gajria, A. Coutinho, P. Yeung & R. White (2017) Burden of Alcohol Abuse or Dependence Among Long-term Opioid Users With Chronic Noncancer Pain. *J Manag Care Spec Pharm*, 23, 718-724.

[3] Larance, B., G. Campbell, A. Peacock, S. Nielsen, R. Bruno, W. Hall, N. Lintzeris, M. Cohen & L. Degenhardt (2016) Pain, alcohol use disorders and risky patterns of drinking among people with chronic non-cancer pain receiving long-term opioid therapy. *Drug Alcohol Depend*, 162, 79-87.

[4] Hillebrand, J., J. Marsden, E. Finch & J. Strang (2001) Excessive alcohol consumption and drinking expectations among clients in methadone maintenance. *J Subst Abuse Treat*, 21, 155-160.

[5] Dobler-Mikola, A., J. Hattenschwiler, D. Meili, T. Beck, E. Boni & J. Modestin (2005) Patterns of heroin, cocaine, and alcohol abuse during long-term methadone maintenance treatment. *J Subst Abuse Treat*, 29, 259-65.

[6] Koski A, I. Ojanperä, E. Vuori (2003) Interaction of alcohol and drugs in fatal poisonings. *Hum Exp Toxicol.* 22, 281-7.

Despite this well-known risk, at least one-third to one-half of patients receiving chronic prescription opioid therapy exhibit concurrent alcohol abuse or dependence[7,8], and the U.S. Centers for Disease Control and Prevention ("CDC") has reported that nearly one-quarter of prescription opioid overdose deaths are mediated by concurrent alcohol consumption[1,]

SafeRx is currently focused on the development of our patented class of AROs, oral solid opioid analgesics that combine active pharmaceutical ingredients ("APIs") in order to deter the concurrent consumption of alcohol. SafeRx's patented alcohol-resistant formulations consist of an approved prescription opioid plus disulfiram, a well-established aldehyde dehydrogenase inhibitor ("ALDI") that interferes with alcohol metabolism. These active pharmaceutical ingredients have already been individually approved by the U. S. Food and Drug Administration ("FDA") for their respective indications of analgesia and alcohol-deterrence. If patients avoid alcohol as instructed, the disulfiram component remains inert while the opioid component provides the prescribed pain relief. If, however, a patient inappropriately consumes alcohol while taking an ARO, they experience an acute noxious reaction characterized by dizziness, headache, and nausea/vomiting that deters further alcohol consumption. SafeRx aims to provide physicians and patients a safer option for the management of moderate to severe pain that pharmacologically deters dangerous and inappropriate alcohol consumption while taking the pain medication.

SafeRx has developed both a proprietary method and chemical compositions for reducing the risk of overdose, death, or other injury associated with the inappropriate consumption of alcohol in conjunction with prescription opioid pain medication. Although all combination products that include opioids with ALDIs are covered under SafeRx's intellectual property, initial product development efforts will focus on only two ARO products.

We plan to develop our two initial products, OxARO® IR and MethARO® IR, on a parallel basis because of their synergistic approaches for regulatory pathways and operational resources. OxARO® IR and MethARO® IR combine an approved prescription opioid (oxycodone hydrochloride or methadone hydrochloride, respectively) with disulfiram into fixed-dose immediate release formulations in an excipient matrix that prevents separation of the active pharmaceutical ingredients.

Oxycodone and methadone comprise nearly half of all opioid prescriptions filled in the United States, and these two drugs routinely account for the greatest number of prescription overdose-related fatalities. These medications both have a well-established track record of clinical efficacy and are FDA-approved for the treatment of moderate-to-severe pain across a range of patient populations; methadone carries an additional indication for maintenance treatment of opioid use disorder (aka opioid addiction). Similarly, disulfiram was selected for our initial AROs for its alcohol-deterrent properties because the alcohol-disulfiram reaction is well-characterized. Furthermore, disulfiram is the only medication in its class to be FDA-approved for the indication of enforced abstinence from alcohol.

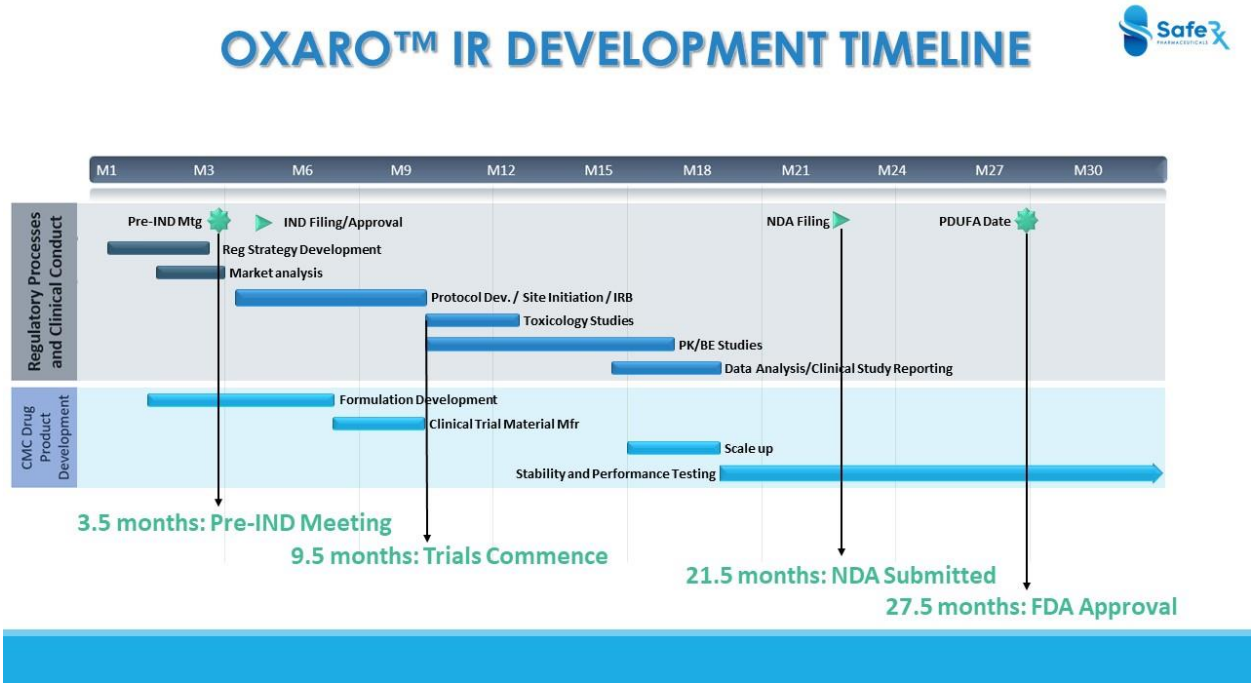
By selecting three APIs for which decades of high-quality pre-clinical and clinical safety and efficacy data exist, SafeRx anticipates leveraging FDA's 505(b)2 regulatory pathway for approval for these initial ARO products, see "Regulation" below. Because AROs address a designated national public health emergency, they are also expected to qualify for priority review with FDA.

**Milestones and Timeline**

A high-level process overview with estimated timelines is shown below:

[7] Stenbacka, M., O. Beck, A. Leifman, A. Romelsjo & A. Helander (2007) Problem drinking in relation to treatment outcome among opiate addicts in methadone maintenance treatment. *Drug Alcohol Rev*, 26, 55-63.

[8] Senbanjo, R., K. Wolff & J. Marshall (2007) Excessive alcohol consumption is associated with reduced quality of life among methadone patients. *Addiction*, 102, 257-63.




We anticipate beginning this process upon receiving approximately $500,000 in funding, either through this offering, private placements, or other funding.

**Market Overview and Addressable Domestic Markets**

Over 150 million opioid prescriptions are filled every year in the United States. It is estimated that approximately one-third are provided to patients considered high-risk for concurrent alcohol consumption. Despite a moderate reduction in the total number of opioid prescriptions written in recent years, the opioid market has continued to grow. The FDA recognizes the ongoing need for prescription opioids and incentivizes new products but encourages the development of formulations that deter misuse and abuse.

Recent growth of the opioid market has been driven primarily by increased use of branded products, including abuse-deterrent formulations (ADFs), which sell for roughly 10 times the price of their non-deterrent counterparts. Abuse-deterrent formulations are aimed at impeding the known or expected forms of abuse for the specific opioid product, including intranasal (e.g., crushing in order to snort) or intravenous (e.g. dissolving in order to inject) routes of administration. However, in contrast to the CDC data showing nearly one-quarter of fatal prescription opioid overdoses are related to concurrent alcohol consumption, there is little to no direct data on the number of overdoses that can be attributed to such intranasal or intravenous forms of abuse. Existing ADFs have captured far less market share than originally anticipated (less than 6%), largely because these products have not proven effective in reducing overdose risk. There are currently no FDA-approved opioid formulations designed to prevent concurrent alcohol consumption.

**Employees**

SafeRx currently has 1 full time employee (Michael Presti, the CEO of the company) and one part time employee (Ray Sison, the CPO of the company).

**Regulation**

Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act provides for an abbreviated regulatory pathway through which candidate drugs can gain FDA approval without the need for corporate sponsors to replicate safety and efficacy data already established in the public domain. Specifically, per the FDA, "A 505(b)(2) application is an [new drug application] that contains full reports of investigations of safety and effectiveness, 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 or use, including, for example, the FDA's findings of safety and/or effectiveness ("AFSE") for a listed drug or published literature." The 505(b)(2) pathway is intended for drugs that modify an existing approved product, for instance via new dosage formulations, routes of administration, or expansion to a new patient population or different indication.

The 505(b)(2) application pathway enables SafeRx to leverage extensively such prior FDA findings of safety and/or effectiveness, as all the APIs included in the proposed ARO platform products have already undergone the rigorous FDA review and approval process for their intended indications. In so doing, the scope of new data required for FDA approval of these combination products is minimized, thereby reducing significantly the associated product development costs and timelines.

Because AROs address a designated national public health emergency, they are also expected to qualify for priority review by the FDA. A priority review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review).

Given these and other process efficiencies, SafeRx expects FDA approval of both OxARO® IR and MethARO® IR within three years of funding, compared to the approximately nine-year approval process for new drug approvals not subject to the Section 505(b)(2) application process or priority review.

**Intellectual Property**

SafeRx has two issued U.S. utility patents, with two additional U.S. patents and one international patent pending, as well as four registered trademarks with the United States Patent and Trademark Office ("USPTO").

***Issued Patents***

*US10,478,408 (132277-236304): Combination Treatments for Opioid Crisis*

This patent was issued on November 19, 2019. The expiration date, assuming all maintenance fees are timely paid, is January 26, 2038.

The patent includes two independent method claims directed to combination drug therapies for reducing the chances of alcohol mediated opioid overdose or death during maintenance therapy for management of pain.

*US10,881,625 (132277-250662): Combination Treatments for Opioid Crisis*

This patent was granted on January 5, 2021. The expiration date, assuming all maintenance fees are timely paid, is January 26, 2038.

The patent includes two independent claims directed to combination medications. The first is directed to a combination medication comprising an effective amount of one or more opioid medications, an effective amount of one or more aldehyde dehydrogenase inhibitors, and a pharmaceutical carrier. The second independent claim is directed to a combination medication comprising an effective amount of oxycodone, and an effective amount of disulfiram or pharmaceutically acceptable salts thereof, and a pharmaceutically acceptable carrier.

***Pending Patents***

*US Patent Application No. 17/102,010 (132277-259183): Combination Treatments for Opioid Crisis*

This application is a continuation application of US Patent Application No. 16/598,509 (corresponding to issued patent US10,881,625). This application is a continuation application of US Patent Application No. 16/598,509 (corresponding to issued patent US10,881,625), and covers methods of use and combination medications similar to those discussed above, but that include triple combinations in which naloxone is included with the opioid analgesic and disulfiram in order to deter IV administration.

*US Patent Application No. 17/238,459 (Priority to US 63/093,714): Combination Products to Mitigate the Risk of Non-Benzodiazepine Benzodiazepine Agonist Adverse Reaction and Overdose*

This application was filed April 23, 2021. The deadline for filing PCT applications is October 19, 2021.

This application claims a method of reducing the chances of an alcohol-mediated nonbenzodiazepine benzodiazepine receptor agonist ("NBBRA")-related adverse event occurring during NBBRA usage, comprising selecting a subject for NBBRA usage and administering a single composition to the subject, the single composition comprising an effective amount of one or more NBBRAs for the management of a sleep or anxiety disorder, and an effective amount of one or more ALDIs. A second independent claim is directed to a combination medication comprising an effective amount of one or more ALDIs and an effective amount of one or more NBBRAs.

*International Patent Application: Combination Treatments for Opioid Crisis*

This international application was filed under the Patent Cooperation Treaty ("PCT") on January 23, 2019. This PCT application claims priority to 15/881,475 ((corresponding to issued patent US10,478,408).

The PCT application included 19 claims, 2 of which are independent claims. The independent claims are directed to: (1) a method of reducing the chances of alcohol mediated opioid death, comprising administration of a combination medication comprising an effective amount of one or more opioid medications and an effective amount of one or more aldehyde dehydrogenase inhibitors to prevent concomitant alcohol consumption, thereby reducing the risk of alcohol mediated opioid overdose or death and (2) a combination medication comprising an effective amount of one or more opioid medications, and an effective amount of one or more aldehyde dehydrogenase inhibitors and a pharmaceutically acceptable carrier.

- On July 17, 2020, this application entered into the Canadian National Phase with the same claims as those of the PCT. Canadian Application No. 3,089,071 (132277-256168) was published on August 8, 2019, and is currently pending.
- On August 17, 2020, this application entered into the European Regional Phase with 15 claims, two of which are independent. In the European application, the method claim listed above is replaced by a claim to a combination medication comprising an effective amount of one or more opioid medications, and an effective amount of one or more aldehyde dehydrogenase inhibitors for use in treating pain in a manner which prevents concomitant alcohol consumption, thereby reducing the risk of alcohol mediated overdose or death. The bibliographic data of European Application No. 19744389.8 (132277-256169) was published on December 2, 2020, and is currently pending.
- On August 18, 2020, this application entered into the Indian National Phase with 8 claims. The single independent claim is directed to a combination medication that corresponds to the second claim of the PCT application listed above. Indian Patent Application No. 202047035537 (132277-256170) was published in the Indian Patent Office Journal on September 18, 2020, and is currently pending.
- On July 24, 2020, this application entered into the Mexican National Phase with 19 claims, corresponding to the same claims as those of the PCT. The Mexican National Phase Application was assigned Patent Application No. MX/a/2020/007860 (132277- 256171), and is currently pending.

***Registered Trademarks***

SafeRx has four USPTO-registered trademarks:

*OxARO (serial number 90233007)*
Filing Date: October 2, 2020
Publication Date: April 6, 2021
Goods and Services: Pharmaceutical preparations, namely, an analgesic for human consumption taken orally

*MethARO (serial number 90233041)*
Filing Date: October 2, 2020
Publication Date: April 6, 2021
Goods and Services: Pharmaceutical preparations, namely, an analgesic for human consumption taken orally

*HydARO (serial number 90233032)*
Filing Date: October 2, 2020
Publication Date: April 6, 2021
Goods and Services: Pharmaceutical preparations, namely, an analgesic for human consumption taken orally

*MorphARO (serial number 90233019)*
Filing Date: October 2, 2020
Publication Date: April 6, 2021
Goods and Services: Pharmaceutical preparations, namely, an analgesic for human consumption taken orally

**Litigation**

The company is not involved in any litigation, and its management is not aware of any pending or threatened legal actions relating to its intellectual property, conduct of its business activities, or otherwise.

**THE COMPANY'S PROPERTY**

The company does not lease any property. The company is currently without a headquarters while management works remotely.

**Due Diligence**

Due diligence by CrowdCheck, Inc.

**RISK FACTORS**

The SEC requires the company to identify risks that are specific to its business and its financial condition. The company is still subject to all the same risks that all companies in its business, and all companies in the economy, are exposed to. These include risks relating to economic downturns, political and economic events and technological developments (such as hacking and the ability to prevent hacking). Additionally, early-stage companies are inherently more risky than more developed companies. You should consider general risks as well as specific risks when deciding whether to invest.

These are the risks that relate to the company:

**Our company is brand new and has no operating history.**
The company was formed as an LLC in 2020 and converted to a Delaware Corporation in 2021. We have no established business operations and it is unclear at this point which, if any, of our current and intended plans may come into fruition and, if they do, which ones will be a success. The company has incurred a net loss and has had not generated any revenue since inception. There is no assurance that the company will ever be able to establish successful business operations, become profitable or generate sufficient revenues to operate our business or pay dividends.

**If the company cannot raise sufficient funds, it will not succeed.**
The company is offering Class B Non-Voting Common Stock in the amount of up to $5,000,000 in this offering, with a Target Offering Amount of $25,000. Even if the maximum amount is raised, the company is likely to need additional funds in the future in order to grow, and if it cannot raise those funds for whatever reason, including reasons relating to the company itself or to the broader economy, it may not survive. If the company manages to raise only the minimum amount of funds sought, it will have to find other sources of funding for some of the plans outlined in "Use of Proceeds."

**Any valuation at this stage is difficult to assess.**
The valuation for the offering was established by the company. Unlike listed companies that are valued publicly through market-driven stock prices, the valuation of private companies, especially startups, is difficult to assess and you may risk overpaying for your investment.

**The company operates in a highly regulated industry.**
The company is subject to extensive regulation and failure to comply with such regulation could have an adverse effect on the company's business. Further, currently the company believes that it can take advantage of a 505(b)(2) new drug application pathway and priority review with the FDA, substantially reducing the time needed for FDA approval relative to a traditional 505(b)(1) application typically used for novel drugs that have not previously been studied or approved. If there are changes in the regulatory environment or in the interpretation of the regulation for the company's product (including FDA requirements) or the company is unable to take advantage of priority review or there are unforeseen material changes to federally-mandated opioid prescribing policies, it could delay our ability to bring our product to market, if at all, and could have a material adverse effect on our operations.

**We may not receive the requisite approval from the FDA for the use of our products.**
If we are unable to receive approval from the FDA for the use our products, we will not be able to market and sell our products. Obtaining such authorization is dependent upon a number of factors which are not under our control.

**AROs will require market acceptance to be successful. Failure to gain market acceptance would impact the company's revenues and may materially impair its ability to continue its business.**
Even if we are able to get FDA approval for the use of our products, the commercial success of AROs will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to

competing products and treatments. There can be no assurance that these parties will adopt the use of AROs. Market acceptance of, and demand for, any product that the company may develop and commercialize will depend on many factors, both within and outside of the company's control. If AROs fail to gain market acceptance, the company may be unable to earn sufficient revenue to continue its business. Further, there may be subsequent changes in pain management and some of the opioids and pharmaceuticals that we plan to use as the basis for our AROs may become obsolete and therefore our products may also become obsolete.

**The company may face substantial competition, which may result in others discovering, developing, or commercializing products more successfully than the company does.**
In general, the chronic pain industry is subject to intense competition and rapid and significant technological change. Although all combination products that include opioids with ALDIs are covered under SafeRx's intellectual property, there may be many potential competitors with different solutions to reduce the danger of alcohol-related opioid abuse, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes, production and manufacturing, achieving FDA approval for products, and sales and marketing of such approved products.

**Product reliability, safety and effectiveness concerns can have significant negative impacts on sales and results of operations, lead to litigation and cause reputational damage.**
Concerns about product safety, whether raised internally or by litigants, regulators or consumer advocates, and whether or not based on scientific evidence, can result in safety alerts, product recalls, governmental investigations, regulatory action on the part of the FDA (or its counterpart in other countries), private claims and lawsuits, payment of fines and settlements, declining sales and reputational damage. These circumstances can also result in damage to brand image, brand equity and consumer trust in the company's products. Product recalls have in the past, and could in the future, prompt government investigations and inspections, the shutdown of manufacturing facilities, continued product shortages and related sales declines, significant remediation costs, reputational damage, possible civil penalties and criminal prosecution.

**Interruptions and delays in future manufacturing operations could adversely affect the Company's business, sales and reputation.**
The company's future manufacture of AROs will require the timely delivery of sufficient amounts of complex, high-quality components and materials. The Company may face unanticipated interruptions and delays in manufacturing through its internal or external supply chain. Manufacturing disruptions can occur for many reasons including regulatory action, production quality deviations or safety issues, labor disputes, site-specific incidents (such as fires), natural disasters such as hurricanes and other severe weather events, raw material shortages, political unrest and terrorist attacks. Such delays and difficulties in manufacturing can result in product shortages, declines in sales and reputational impact as well as significant remediation and related costs associated with addressing the shortage.

**The company depends on key personnel and faces challenges recruiting needed personnel.**
The company's future success depends on the efforts of a small number of key personnel. In addition, due to its limited financial resources and the specialized expertise required, it may not be able to recruit the individuals needed for its business needs. There can be no assurance that the company will be successful in attracting and retaining the personnel the company requires to operate and be innovative.

**If the company cannot protect, maintain and, if necessary, enforce its intellectual property rights, its ability to develop and commercialize products will be adversely impacted.**
The company's success, in large part, depends on its ability to protect and maintain the proprietary nature of its technology. The company must prosecute and maintain its existing patents and obtain new patents. Some of the company's proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with the company. The company cannot guarantee that it will develop proprietary products that are patentable, and that, if issued, any patent will give a competitive advantage

or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. The company cannot assure you that its means of protecting its proprietary rights will suffice or that others will not independently develop competitive technology or design around patents or other intellectual property rights issued to the company. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that the company or its licensors have obtained or obtain in the future may be challenged, invalidated, or unenforceable. If necessary, the company will initiate actions to protect its intellectual property, which can be costly and time consuming.

**The company will depend upon strategic relationships to develop, exploit, and manufacture its products. If these relationships are not successful, the company may not be able to capitalize on the market potential of these products.**

The near and long-term viability of the company's products will depend, in part, on its ability to successfully establish new strategic collaborations with hospitals, insurance companies, manufacturers and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of the company's financial, regulatory, or intellectual property position. If the company fails to establish a sufficient number of collaborations on acceptable terms, it may not be able to commercialize its products or generate sufficient revenue to fund further research and development efforts.

***Risks Related to the Securities***

**Our founder has control over all stockholder decisions because he controls a substantial majority of our voting stock.**

As a result of the Class A Voting Common Stock that he holds, Michael Presti, our founder and Chief Executive Officer will be able to exercise voting rights with respect to an aggregate of 19,466,250 shares of Class A Voting Common Stock, which will represent approximately 92.3% of the voting power of our outstanding capital stock immediately following this offering. The Class B Non-Voting Common Stock issued in this offering will not dilute our co-founders' voting control because the Class B Non-Voting Common Stock has no voting rights. As a result, Dr. Presti has the ability to control the outcome of all matters submitted to our stockholders for approval, including the election, removal, and replacement of directors and any merger, consolidation, or sale of all or substantially all of our assets.

**Our valuation and our offering price have been established internally and are difficult to assess.**

SafeRx has set the price of its Class B Non-Voting Common Stock at $2.21 per share. Valuations for companies at this stage are generally purely speculative. We have not generated any revenues so far. Our valuation has not been validated by any independent third party and may decrease precipitously in the future. It is a question of whether you, the investor, are willing to pay this price for a percentage ownership of a start-up company. The issuance of additional shares of Common Stock, or additional option grants may dilute the value of your holdings. You should not invest if you disagree with this valuation. See "Dilution" for more information.

**Neither the offering nor the Class B Non-Voting Common Stock have been registered under federal or state securities laws, leading to an absence of certain regulation applicable to the company.**

No governmental agency has reviewed or passed upon this offering, the company or any securities of the company. The company also has relied on exemptions from securities registration requirements under applicable state securities laws. Investors in the company, therefore, will not receive any of the benefits that such registration would otherwise provide. Prospective investors must therefore assess the adequacy of disclosure and the fairness of the terms of this offering on their own or in conjunction with their personal advisors.

**No guarantee of return on investment.**

There is no assurance that a purchaser will realize a return on its investment or that it will not lose its entire investment. For this reason, each purchaser should read the Form C and all Exhibits carefully and should consult with its own attorney and business advisor prior to making any investment decision.

**The company's management has discretion as to use of proceeds.**
The net proceeds from this offering will be used for the purposes described under "Use of Proceeds." The company reserves the right to use the funds obtained from this offering for other similar purposes not presently contemplated which it deems to be in the best interests of the company and its investors in order to address changed circumstances or opportunities. As a result of the foregoing, the success of the company will be substantially dependent upon the discretion and judgment of management with respect to application and allocation of the net proceeds of this offering. Investors for the Class B Non-Voting Common Stock hereby will be entrusting their funds to the company's management, upon whose judgment and discretion the investors must depend.

**Future fundraising may affect the rights of investors.**
In order to expand, the company is likely to raise funds again in the future, either by offerings of securities or through borrowing from banks or other sources. The terms of future capital raising, such as loan agreements, may include covenants that give creditors greater rights over the financial resources of the company.

***Risks Related to COVID-19***

**The company's results of operations may be negatively impacted by the coronavirus outbreak.**
The continued spread of COVID-19 has led to severe disruption and volatility in the global capital markets, which could increase the company's cost of capital and adversely affect its ability to access the capital markets in the future. It is possible that the continued spread of COVID-19 could cause a further economic slowdown or recession or cause other unpredictable events, each of which could adversely affect the company's business, results of operations, or financial condition. The extent to which COVID-19 affects the company's financial results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 outbreak and the actions to contain the outbreak or treat its impact, among others. Moreover, the COVID-19 outbreak has had and may continue to have indeterminable adverse effects on general commercial activity and the world economy, and the company's business and results of operations could be adversely affected to the extent that COVID-19 or any other pandemic harms the global economy generally.

**Actual or threatened epidemics, pandemics, outbreaks, or other public health crises may adversely affect the company's business.**
The company's business could be materially and adversely affected by the risks, or the public perception of the risks, related to an epidemic, pandemic, outbreak, or other public health crisis, such as the recent outbreak of COVID-19. The risk, or public perception of the risk, of a pandemic or media coverage of infectious diseases could adversely affect the value of the Class B Non-Voting Common Stock and the financial condition of the company's investors or prospective investors, resulting in reduced demand for the Class B Non-Voting Common Stock generally. Further, such risks could result in persons avoiding appearing at in-person health care appointments. "Shelter-in-place" or other such orders by governmental entities could also disrupt the company's operations, if those employees of the company who cannot perform their duties from home are unable to report to work.

**DIRECTORS, EXECUTIVE OFFICERS AND EMPLOYEES**

This table shows the principal people on the company's team:

| Name | Position | Term of Office | Approx. hours per week (if not full time) |
|---|---|---|---|
| Executive Officers: | | | |

| | | | |
|---|---|---|---|
| Michael Presti | President, Chief Executive Officer, and Secretary | CEO from June 22, 2020 to Present; President and Secretary from May 10, 2021 to Present | Full -Time |
| Ray Sison | Chief Product Officer | CPO from October 23, 2020 to Present | 12.5 |
| Directors: | | | |
| Michael Presti | Director | June 22, 2020 until Present | |

***Michael Presti: President, Chief Executive Officer, Secretary and Director***

Michael Presti MD PhD, is the founder of SafeRx and has served as the CEO and initial director since June 22, 2020. He was also named the President and Secretary of SafeRx as part of the company's conversion into a Delaware corporation on May 10, 2021. Prior to committing full-time to SafeRx Pharmaceuticals, Dr. Presti worked as a staff physician with Montage Medical Group from May 2019 to January 2021. Before that, he served as Medical Director of both the Asante Rogue Regional Sleep Center from April 2016 to April 2019 as a Medical Director for the Asante Three Rivers Sleep Center from April 2016 to April 2019 and as a Staff Physician with Asante Physician Partners from April 2016 to April 2019.

Dr. Presti received his MD and PhD in Neuroscience from the University of Florida and completed his Neurology residency and fellowship training at the Mayo Clinic Rochester. He also holds a Master's degree in Business Management. He believes in the duty of a physician to do no harm, and is passionate about developing pharmaceutical options that reduce the risk of overdose and other adverse events. Dr. Presti is leading the company in strategic planning, pre-clinical and clinical testing design, and fundraising.

***Ray Sison, MS: Chief Product Officer***

Mr. Sison has served as the Chief Product Officer since October 30, 2020. He has over 30 years of pharmaceutical drug development, manufacturing, and commercialization. Prior to SafeRx, Mr. Sison led drug product development programs at AHP from September 1991 to May 1995 and Ivax from May 1995 to June 1998, resulting in approvals of both new drug applications and abbreviated new drug applications. He previously founded Vinco Pharma Solutions and xCell Strategic Consulting serving development and clinical stage biotech clients at Vinco from June 2020 to October 2020 and xCell from May 2014 to October 2020, and contributed to the product launches of Roxybond and Morphabond.

**ADVISORY BOARD**

Our company benefits from an advisory board of highly respected individuals. To date, we have compensated our advisory board in common stock (including restricted common stock).

***Jamie Grooms: Executive Board Member***

Mr. Grooms is the former CEO of Florida Institute for Commercialization of Public Research. He is a visionary and innovator in medical technology who has successfully launched, managed or advised numerous biotech startup companies. Mr. Grooms is co-founder of Regeneration Technologies (NASDAQ: RTIX), AxoGen, Inc (NASDAQ: AXGN), and NeXtGen Biologics, and serves as Chairman and Board member of multiple other biotech and pharma companies.

***James Parino, PhD, MBA: Board Member***

Dr. Parino is the managing director and co-head of the M&A Buyside Advisory at Fifth Third Securities and is also managing director at Praxis Partners LLC. He is on faculty at the University of Florida Warrington School of Business and is considered an expert in corporate valuation, venture finance, M&A, entrepreneurship, corporate strategy, and cross-border acquisitions. Dr. Parino is a CPA with over 30 years of operational, strategic, and transactional M&A advisory experience.

***Marlo Tan Walpole: Board Member***
Ms. Walpole has over 20 years of experience successfully managing all aspects of Product Development in both private and publicly held companies in the tissue, medical device, and biologic/pharmaceutical industries. Her expertise is in navigating product development in startup to mid-size companies. Ms. Walpole has lead product development at AuxThera, Inc., AxoGen, Inc. (NASDAQ: AXGN), RTI Surgical, Inc. (NASDAQ: RTIX), US Biomaterials, and OxThera, Inc. She holds her MS in Biomedical Engineering from the University of Memphis in collaboration with the University of Tennessee Health Science Center.

**OWNERSHIP AND CAPITAL STRUCTURE; RIGHTS OF THE SECURITIES**

**Ownership**

The following table shows who owns more than 20% of company's voting securities as of May 10, 2021:

| Name of Beneficial owner | Amount and class of securities held | Percent of voting power prior to the Offering |
|---|---|---|
| Michael Presti | 19,466,250 Class A Voting Common Stock | 92.3% |

**USE OF PROCEEDS**

The company anticipates using the proceeds from this offering in the following manner:

| Purpose or Use of Funds | Allocation After Offering Expenses for a $25,000 Raise | Allocation After Offering for a $5,000,000 Raise |
|---|---|---|
| IND Filing | | $200,000 |
| Regulatory Strategy, Market Access Research, and Pre-IND Meeting | | $250,000 |
| Formulation Development | | $260,000 |
| Clinical Study Initiation | | $300,000 |
| Clinical Conduct | | $650,000 |
| Clinical Trial Materials Manufacturing | | $900,000 |
| General and Administrative | $25,000 | $940,000* |
| Registration Batch Manufacturing | | $1,500,000 |

* Includes salaries of $225,000 per annum for the CEO and $200,000 per annum for the Chief Product Officer.

**The identified uses of proceeds are subject to change at the sole direction of the officers and directors based on the business needs of the company.**

**FINANCIAL DISCUSSION**

**Financial statements**

The company's financial statements for the period from inception on June 22, 2020 and ended December 31, 2020 have been audited by BF Borgers CPA PC. The following discussion should be read in conjunction with our audited financial statements and the related notes included in this Offering Statement.

***Operating Results***

The company did not have any revenues in 2020. The company's expenses for the period ended December 31, 2020 were $97,638. The company's net losses for the period ended December 31, 2020, were $822,403. Of the $822,403, $724,765 was attributable to derivative liabilities associated with outstanding convertible notes.

***Liquidity and Capital Resources***

As of December 31, 2020, the company held $175,149 in cash and cash equivalents. To date the company has funded operations from private placements of convertible notes, for which it received $280,000.

The company may require the continued infusion of new capital to continue business operations. Since the year end until May 6, 2021, the company has raised an additional $100,000 and spent approximately $75,000 on expenses.

Receiving proceeds from this offering under Regulation Crowdfunding, or from other sources of financing, is necessary for the viability of the company. The company's minimum current burn rate is less than $1,000 per month, excluding costs associated with this offering. However, as we continue to fundraise and develop our operations, we anticipate increasing our monthly costs proportionately. The company believes that upon receiving the maximum proceeds from this offering under Regulation Crowdfunding, the company could continue to grow and be viable for the next 12 months. In addition, the company plans to continue to try to raise additional capital through Regulation A offerings, equity issuances, or any other method available to the company. Absent additional capital, the company may be forced to significantly reduce expenses and could become insolvent.

**Plan of Operations and Milestones**

The company has established the following four principal milestones in the clinical development plan for each of the intended ARO products:

- ***Investigational New Drug approval***, through which permission to start human clinical trials is granted. SafeRx anticipates achieving this milestone within four months of program launch.
- ***Commencement of clinical trials***, at which time the planned pharmacokinetic/bioequivalency studies will be performed on the finalized combination drug formulations. SafeRx anticipates reaching this milestone within 10 months of program launch.
- ***New drug application (NDA) submission***, marking the conclusion of clinical trials, data analyses, and study reporting, at which point a formal request for FDA review will be made. SafeRx anticipates reaching this milestone within 22 months of program launch.
- ***NDA determination by the FDA***, marking the date of approval or rejection of the application. If as expected the ARO product NDAs qualify for priority review with the FDA, this determination will be due within 6 months of NDA submission, corresponding with approximately 28 months from program launch. If not treated according to priority review policy as expected, FDA action is expected within 12 months of NDA submission, corresponding with 34 months from program launch.

**Trends and COVID-19**

In March 2020, the World Health Organization made the assessment that the outbreak of a novel coronavirus (COVID-19) can be characterized as a pandemic. As a result, uncertainties have arisen that may have a significant negative impact on the operating activities and results of the company. The occurrence and extent of such an impact will depend on future developments, including (i) the duration and spread of the virus, (ii) government quarantine measures, (iii) voluntary and precautionary restrictions on travel or meetings, (iv) the effects on the financial markets, and (v) the effects on the economy overall, all of which are uncertain.

**RELATED PARTY TRANSACTIONS**

None.

**RECENT OFFERINGS OF SECURITIES**

In the third quarter of 2020, the company issued Convertible Promissory Notes in the aggregate principal amount of $180,000 under Section 4(a)(2) of the Securities Act. In the second quarter of 2021, the company issued an additional Convertible Promissory Note in the principal amount of $100,000 000 under Section 4(a)(2) of the Securities Act. The funds received were used for working capital.

**SECURITIES BEING OFFERED AND RIGHTS OF THE SECURITIES OF THE COMPANY**

*The following descriptions summarize important terms of our capital stock. This summary reflects SafeRx's Certificate of Incorporation and does not purport to be complete and is qualified in its entirety by the Certificate of Incorporation and its Bylaws. For a complete description the company's capital stock, you should refer to our Certificate of Incorporation and our Bylaws and applicable provisions of the Delaware General Corporation Law.*

**General**

The Company's authorized securities consist of up to 28,034,542 shares of common stock, of which at least 21,099,675 are Class A Voting Common Stock and at least 2,262,443 are Class B Non-Voting Common Stock, and $280,000 of Convertible Promissory Notes. As of May 10, 2021, there were 21,099,675 shares of Class A Voting Common Stock outstanding. For this offering, the company is issuing Class B Non-Voting Common Stock.

Class B Non-Voting Common Stock has the same rights and powers of, ranks equally to, shares ratably with and is identical in all respects, and as to all matters to Class A Voting Common Stock; except that our Class B Non-Voting Common Stock is non-voting and is not entitled to any votes on any matter that is submitted to a vote of our stockholders, except as required by Delaware Law.

**Common Stock**

***Voting Rights***

Class B Non-Voting Common Stock is not entitled to any votes on any matter that is submitted to a vote of our stockholders, except as required by Delaware law.

***Distribution Rights***

The holders of the Class A Voting Common Stock and Class B Non-Voting Common Stock shall be entitled to receive, on a pari passu basis, when and as declared by the Board of Directors, out of any assets of the Company legally available therefore, such dividends as may be declared from time to time by the Board of Directors.

***Right to Receive Liquidation Distributions***

In the event of the company's liquidation, or winding up, whether voluntary or involuntary, subject to the rights of any preferred stock that may then be outstanding, the assets of the company legally available for distribution to stockholders shall be distributed on an equal priority, pro-rata basis to the holders of Class A Voting Common Stock and Class B Non-Voting Common Stock, treated as a single class.

***Other Rights***

Holders of our Class A Voting Common Stock and Class B Non-Voting Common Stock have no preemptive, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our Class A Voting Common Stock and Class B Non-Voting Common Stock.

**Convertible Promissory Notes**

In the third quarter of 2020 and second quarter of 2021, the company issued Convertible Promissory Notes in the aggregate principal amount of $280,000. These notes have an interest rate of 8% per annum. $80,000 of the Convertible Promissory Notes are due in July 2023, $100,000 of the Convertible Promissory Notes are due in August 2023, and $100,000 of the Convertible Promissory Notes are due in May 2024.

**What it Means to be a Minority Holder**

As an investor in Class B Non-Voting Common Stock of the company, you will not have any rights in regards to the corporate actions of the company, including additional issuances of securities, company repurchases of securities, a sale of the company or its significant assets, or company transactions with related parties.

**Transferability of securities**

For a year, the securities can only be resold:

- In an IPO or other public offering registered with the SEC;
- To the company;
- To an accredited investor; and
- To a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

**Transfer Agent**

The company has selected KoreConX, an SEC-registered securities transfer agent, to act as its transfer agent. They will be responsible for keeping track of who owns the company's securities.

**DILUTION**

Investors should understand the potential for dilution. The investor's stake in a company could be diluted due to the company issuing additional shares. In other words, when the company issues more shares, the percentage of the company that you own will go down, even though the value of the company may go up. You will own a smaller piece of a larger company. This increase in number of shares outstanding could result from a stock offering (such as an initial public offering, another crowdfunding round, a venture capital round, angel investment), employees exercising stock options, or by conversion of certain instruments (e.g., convertible bonds, preferred shares or warrants) into stock.

If the company decides to issue more shares, an investor could experience value dilution, with each share being worth less than before, and control dilution, with the total percentage an investor owns being less than before. There may also be earnings dilution, with a reduction in the amount earned per share (though this typically occurs only if the company offers dividends, and most early-stage companies are unlikely to offer dividends, preferring to invest any earnings into the company).

The type of dilution that hurts early-stage investors most occurs when the company sells more shares in a "down round," meaning at a lower valuation than in earlier offerings. An example of how this might occur is as follows (numbers are for illustrative purposes only):

- In June 2020 Jane invests $20,000 for shares that represent 2% of a company valued at $1 million.
- In December the company is doing very well and sells $5 million in shares to venture capitalists on a valuation (before the new investment) of $10 million. Jane now owns only 1.3% of the company but her stake is worth $200,000.
- In June 2021 the company has run into serious problems and in order to stay afloat it raises $1 million at a valuation of only $2 million (the "down round"). Jane now owns only 0.89% of the company and her stake is worth only $26,660.

This type of dilution might also happen upon conversion of convertible notes into shares. Typically, the terms of convertible notes issued by early-stage companies provide that in the event of another round of financing, the holders of the convertible notes get to convert their notes into equity at a "discount" to the price paid by the new investors, i.e., they get more shares than the new investors would for the same price. Additionally, convertible notes may have a "price cap" on the conversion price, which effectively acts as a share price ceiling. Either way, the holders of the convertible notes get more shares for their money than new investors. In the event that the financing is a "down round" the holders of the convertible notes will dilute existing equity holders, and even more than the new investors do, because they get more shares for their money. Investors should pay careful attention to the aggregate total amount of convertible notes that the company has issued (and may issue in the future, and the terms of those notes.

If you are making an investment expecting to own a certain percentage of the company or expecting each share to hold a certain amount of value, it's important to realize how the value of those shares can decrease by actions taken by the company. Dilution can make drastic changes to the value of each share, ownership percentage, voting control, and earnings per share.

**Valuation**

As discussed in "Dilution" above, the valuation of the company will determine the amount by which the investor's stake is diluted in the future. An early-stage company typically sells its shares (or grants options over its shares) to its founders and early employees at a very low cash cost, because they are, in effect, putting their "sweat equity" into the company. When the company seeks cash investments from outside investors, like you, the new investors typically pay a much larger sum for their shares than the founders or earlier investors, which means that the cash value of your stake is immediately diluted because each share of the same type is worth the same amount, and you paid more for your shares than earlier investors did for theirs.

There are several ways to value a company, and none of them is perfect and all of them involve a certain amount of guesswork. The same method can produce a different valuation if used by a different person.

*Liquidation Value* — The amount for which the assets of the company can be sold, minus the liabilities owed, e.g., the assets of a bakery include the cake mixers, ingredients, baking tins, etc. The liabilities of a bakery include the cost of rent or mortgage on the bakery. However, this value does not reflect the potential value of a business, e.g., the value of the secret recipe. The value for most startups lies in their potential, as many early-stage companies

do not have many assets (they probably need to raise funds through a securities offering in order to purchase some equipment).

*Book Value* — This is based on analysis of the company's financial statements, usually looking at the company's balance sheet as prepared by its accountants. However, the balance sheet only looks at costs (i.e., what was paid for the asset), and does not consider whether the asset has increased in value over time. In addition, some intangible assets, such as patents, trademarks or trade names, are very valuable but are not usually represented at their market value on the balance sheet.

*Earnings Approach* — This is based on what the investor will pay (the present value) for what the investor expects to obtain in the future (the future return), taking into account inflation, the lost opportunity to participate in other investments, the risk of not receiving the return. However, predictions of the future are uncertain and valuation of future returns is a best guess.

Different methods of valuation produce a different answer as to what your investment is worth. Typically, liquidation value and book value will produce a lower valuation than the earnings approach. However, the earnings approach is also most likely to be risky as it is based on many assumptions about the future, while the liquidation value and book value are much more conservative.

Future investors (including people seeking to acquire the company) may value the company differently. They may use a different valuation method, or different assumptions about the company's business and its market. Different valuations may mean that the value assigned to your investment changes. It frequently happens that when a large institutional investor such as a venture capitalist makes an investment in a company, it values the company at a lower price than the initial investors did. If this happens, the value of the investment will go down.

**REGULATORY INFORMATION**

**Disqualification**

Neither the company nor any of its officers or managing members are disqualified from relying on Regulation Crowdfunding.

**Annual reports**

The company has not filed annual reports to date. Any annual reports will be posted on the company's page with is transfer agent, KoreConx at http://saferx.koreconx.com/.

**Compliance failure**

The company has not previously failed to comply with the requirements of Regulation Crowdfunding.

**INVESTING PROCESS**

**Information Regarding Length of Time of Offering**

Investment Cancellations: Investors will have up to 48 hours prior to the end of the offering period to change their minds and cancel their investment commitments for any reason. Once the offering period is within 48 hours of ending, investors will not be able to cancel for any reason, even if they make a commitment during this period.

Notifications: Investors will receive periodic notifications regarding certain events pertaining to this offering, such as the company reaching its offering target, the company making an early closing, the company making material changes to its Form C, and the offering closing at its target date.

Material Changes: Material changes to an offering include but are not limited to: a change in minimum offering amount, change in security price, change in management, etc. If an issuing company makes a material change to

the offering terms or other information disclosed, including a change to the offering deadline, investors will be given five business days to reconfirm their investment commitment. If investors do not reconfirm, their investment will be cancelled and the funds will be returned.

Rolling and Early Closings: The company may elect to undertake rolling closings, or an early closing after it has received investment interests for its target offering amount. During a rolling closing, those investors that have committed funds will be provided five days' notice prior to acceptance of their subscriptions, release of funds to the company, and issuance of securities to the investors. During this time, the company may continue soliciting investors and receiving additional investment commitments. Investors should note that if investors have already received their securities, they will not be required to reconfirm upon the filing of a material amendment to the Form C. In an early closing, the offering will terminate upon the new target date, which must be at least five days from the date of the notice.

**Investor Limitations**

Investors are limited in how much they can invest on all crowdfunding offerings during any 12-month period. The limitation on how much they can invest depends on their net worth (excluding the value of their primary residence) and annual income. If either their annual income or net worth is less than $107,000, then during any 12-month period, they can invest up to the greater of either $2,200 or 5% of the greater of their annual income or Net worth. If both their annual income and net worth are equal to or more than $107,000, then during any 12-month period, they can invest up to 10% of annual income or net worth, whichever is greater, but their investments cannot exceed $107,000. If the investor is an "accredited investor" as defined under Rule 501 of Regulation D under the Securities Act, as amended, no investment limits apply.

**Updates**

Information regarding updates to the offering and to subscribe can be found at https://www.investinsaferx.com/.