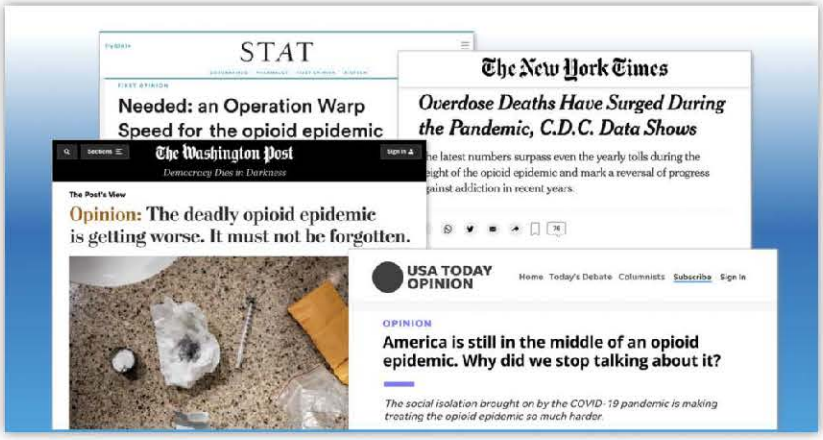
A NATIONAL CRISIS



OVERVIEW

The American opioid crisis is a public health emergency. In 2017, more than two of every three drug overdose deaths—70,200 in that year alone—involved an opioid. The risk of overdose increases dramatically when opioids are combined with alcohol because these substances interact in the body to produce much more intense suppression of the nervous system.

Patients are routinely counseled about the risks of mixing alcohol with opioids, yet 36 – 61% of patients on chronic therapy admit to drinking with their prescribed opioid. Those with a known history of alcohol abuse or addiction are five times more likely to overdose. Accordingly, data from the CDC has shown that nearly one-quarter (22.1%) of fatal prescription opioid overdoses involve alcohol consumption.

Despite such compelling data, this dimension of the opioid crisis has remained largely unaddressed by the pharmaceutical industry. Although some "abuse deterrent" opioid formulations have been developed, none are designed to prevent the co-consumption of alcohol with the opioid. And professional medical practice alternatives such as patient counseling and "medication contracts" are well-meaning, but have failed to provide an effective solution to prevent so many tragic outcomes.

We understand that there is no way to completely eliminate the risk of opioid misuse, abuse, and overdose. However, we believe that by preventing certain high-risk patients from drinking with their prescribed opioid, SafeRX's new, patented, alcohol-resistant opioids (AROs) have the potential to save thousands of lives every year. These AROs are expected to be enthusiastically adopted by pain medicine specialists and other prescribers who currently have no effective means of preventing their patients from making this all-too-often deadly mistake.

How Our Products Work

SafeRX's novel class of alcohol-resistant opioids are fixed-dose combinations that include:

An FDA approved opioid, which acts as an analgesic (painkiller)
An FDA-approved ALDI, which acts as an alcohol deterrent
A tamper-resistant formulation—i.e., the opioid and ALDI, combined in a single-dose matrix, cannot be easily separated

A Closer look at the Biological Process:

If taken as directed—without alcohol—the first component of our ARO product, the opioid, will act as a strong painkiller (analgesic), and the second component, the aldehyde dehydrogenase inhibitor (ALDI), will remain inactive and go unnoticed by the patient. If, however, the patient consumes alcohol with the product, the ALDI will rapidly produce a powerful noxious reaction: severe flushing, headaches, nausea, and vomiting (known as the disulfiram-alcohol reaction).

Our Path to Profits, Value for the Firm, and Liquidity for Our Shareholders:

We intend to arrange a licensing agreement that becomes effective only after a New Drug Application is submitted with the FDA, in order to maximize returns for our shareholders.

With each step to approval, we expect our company gain value, as we get one step closer to our goal. This is why we intend to divide our total intended capital raise into two rounds: a Series A round of $5M, followed by further series of fundraising (after IND approvals for the OxARO® IR and MethARO® IR clinical development programs have been issued and investment risk is further reduced). We are confident that quality New Drug Application submissions for both products can be achieved within 24 months of Series A funding.

Following either NDA submission or FDA approval, we expect to license the ARO platform of products or sell the technology or company outright to an established pharmaceutical partner already operating in the opioid market.

As the FDA is widely regarded as the gold standard regulatory authority, gaining access to the European Union, Mexico, India, and other global markets following such approval is generally a far simpler task. And international patent applications are currently pending in those markets.

Because all the active pharmaceutical ingredients (APIs) included in our ARO platform have already been approved for their respective indications, prior Agency Findings of Safety and Efficacy (AFSE) for these *'reference standards'* can be used to support the intended new drug applications (NDAs). This reduces regulatory uncertainty and dramatically narrows the scope of new trial data required to complete these NDAs. In fact, the only new studies we intend to perform are those needed to establish ***bioequivalence,*** meaning that, when administered together in the intended combination tablets, the corresponding drug concentrations in the body over time (i.e., the "PK profiles") are comparable to those measured when the reference drugs are administered individually. And given their non-overlapping metabolic pathways and distinct mechanisms of action (they effect different parts of the body), there is minimal perceived risk of the intended APIs for either OxARO® IR or MethARO® IR exhibiting drug-drug interactions that would result in altered PK profiles.

Next, the immediate-release (IR) formulations selected for these first two products also convey significant advantages vis-a-vis bioequivalence. That is, in contrast to the engineering challenges associated with mirroring PK profiles of extended-release reference products, which often involve complex formulation technology or manufacturing processes that can be difficult to replicate, bioequivalence is much easier to establish in immediate-release formulations. We believe this significantly reduces the technical uncertainty related risk associated with the OxARO® IR and MethARO® IR development programs.

How are Our Products Different from Currently Available Options?

We believe there is no other viable competitor on the market. Although the FDA has encouraged the development of opioid formulations that deter inappropriate use, only a handful of these "abuse-deterrent formulations" are currently marketed, and all of them target inappropriate routes of administration, such as injecting or snorting the opioid. None deter concurrent opioid-alcohol consumption. And although disulfiram, the alcohol deterrent included in ARO products, can be prescribed as a separate, second medication (e.g., Antabuse®), this only works if the patient takes it… and if given the option, patients who want to drink with their opioid simply won't take it.

How Much is Our Target Market Worth?

We have no intention of creating new opioid patients—only to convert those existing patients at risk of alcohol-mediated opioid overdose from conventional prescriptions to our ARO formulations. This represents a sizable market, as an estimated one-third of patients on chronic opioid therapy consume alcohol with their medication and would be more appropriately treated with an ARO. Assuming no growth in total opioid prescriptions, based on CDC data this represents more than 51 million annual opioid prescriptions in the United States. If, as we expect, ARO products sell at a per-unit price (measured in "morphine milli-equivalents," or MME) comparable to that of other branded opioid products, this correlates with an average current prescription price of approximately $237. Assuming no significant change in opioid prescribing patterns or pricing, this suggests an addressable annual domestic market of $12.1B.

How Much of That are We Aiming to Capture?

We developed a multivariate model to simulate revenue projections using a modest set of assumptions. In it, we model market capture assuming a range of adoption rates between 1% and 6% of "convertible" existing opioid prescriptions per year. This resulted in a median projected market share by Year 10 (i.e., after seven full years on market) of approximately 29% of all "convertible" prescriptions, which (assuming no growth in overall opioid prescriptions) would represent 9.9% of all oral opioid analgesic prescriptions.

How Will We Do It?

We intend to license our approved ARO products to an established pharmaceutical company with the existing resources needed to successfully commercialize them. **We expect such a partner will be able to promote and advertise this product as a means of reducing overdoses, hospitalizations, and death.**

COMPANY

SafeRX was formed with a single mission in mind: to reduce the risk of prescription opioid overdose. We understand that the opioid crisis represents a complex problem for which there will never be any single "silver bullet" or panacea, and that a multi-dimensional strategy is necessary. Accordingly, SafeRX has directed our initial focus to developing products that address **a critical dimension of the crisis for which we believe no solutions currently exist—the combination of opioids with alcohol.**

The Problem (Background)

Opioid patients with a history of alcohol problems have been found to be five times more likely to overdose on their medication, and according to data from the CDC, this all-too-common patient mistake of consuming alcohol with a prescribed opioid pain medication contributes to **nearly one-quarter (22.1%) of fatal overdoses, corresponding with another tragic death in the U.S. approximately every 2 ½ hours.** And despite prominent warnings to avoid all alcohol consumption with their medication, studies have shown that 36 – 81% of long-term opioid patients admit to drinking. Yet prescribing physicians currently have no means of effectively preventing such dangerous behavior. Although an FDA-approved drug for maintaining abstinence from alcohol (Antabuse™) has been available for nearly 70 years, it—like all medications—only works if the patient actually takes it. So if a patient wants to drink… they just don't take it, or even fill the prescription.

Our Solution (Product)

SafeRX is developing a simple and elegant solution to this problem—a novel platform of products we refer to as "alcohol-resistant opioids" (AROs). By combining the prescription opioid analgesic of choice with disulfiram (the active pharmaceutical ingredient of Antabuse™) in a single, inseparable matrix based tablet, these ARO products give patients a very straightforward choice: they can take their prescribed opioid as directed, or they can drink alcohol, but they cannot do both without experiencing an extremely noxious reaction characterized by intense dizziness, headache, and vomiting (i.e., the disulfiram-alcohol reaction). We believe our alcohol-resistant opioids have the potential to save thousands of lives and prevent tens of thousands more non-fatal overdoses each year. Additionally, we believe that alcohol-resistant opioids are less likely to be diverted to the black market and sold illegally. Because SafeRX's products can protect **both the patient and the prescriber**, we anticipate an enthusiastic adoption rate by prescribing physicians, and our ARO platform has already garnered support from key opinion leaders in the field.

Our Status

We have recently been awarded patents protecting both the method of combining these drugs as well as the corresponding chemical compositions, and we are now offering shares of SafeRX to support our clinical development path to FDA approval of two inaugural alcohol resistant opioids products, OxARO® IR and MethARO® IR.

Our Advantage

Fortunately, in contrast to the roughly nine-year traditional path to market required of new chemical entities, since all active pharmaceutical ingredients (APIs) used in our ARO platform have already undergone the rigorous safety and efficacy testing required by the FDA for their respective indications (i.e. the two primary components of the ARO are already FDA-approved), we can pursue a more accelerated regulatory pathway known as a "505(b)(2) new drug application."

Similarly, because our products address a national public health emergency, they are anticipated to qualify for Priority Review with the FDA, which typically reduces Agency approval times to less than six months. Given these and other major process efficiencies, we expect to file a new drug application (NDA) for our first ARO product in less than two years (22.5 months) of funding, after which we would expect further Agency action in under six months.

If approved according to this timeframe, these medications could potentially start reducing the chance of opioid/alcohol-related overdoses in less than 2 ½ years. As we move closer to approval, we will decide on one of many possible go-to-market strategies, but a licensing agreement with a trusted pharmaceutical partner is likely the best path to commercialization. This would provide our first two alcohol resistant opioids access to the greatest number of at risk patients in the shortest timeframe and, with that, the potential for a more rapid and robust return for our investors.

HIGHLIGHTS

Having experienced firsthand the pain and loss caused by prescription opioids in communities across our nation, our company is deeply committed to solving this public health emergency. SafeRX was formed with a mission to enhance the safety of prescription medications, and we believe our alcohol-resistant opioids (AROs) represent a game changing new weapon in the battle against the opioid crisis.

These ARO products are designed to prevent patients from making the all too common deadly mistake of drinking alcohol with their prescribed opioid pain medication. We believe they have the potential to save thousands of lives every year in this country and, based on endorsements already received from key opinion leaders in the field of pain medicine, we expect an enthusiastic adoption rate by prescribing physicians once approved. The company has multiple issued USPTO utility patents for these products and international patents in major markets are pending. In addition to our deep pipeline of alcohol-resistant opioid products, the company also has intellectual property opportunities for pharmaceutical products extending beyond the opioid pain market.

- Strong Intellectual Property Portfolio – Market Exclusivity
  - Issued: USPTO #10,478,408 and #10,881,625, "Combination Treatments for Opioid Crisis"
    - Protects both method and chemical composition of alcohol-resistant opioids, a new class of combination medications designed to reduce the risk of alcohol-mediated opioid overdose and adverse events
    - Enforceable in the U.S. through January 2038
  - Patents pending for ARO platform in Canada, Mexico, India, and European Union
  - Patent pending for new class of alcohol-resistant combination medications intended for the treatment of overlap opioid use disorder-alcohol use disorder
  - Patent pending for new class of alcohol-resistant combination medications intended to enhance the safety of medications commonly used in the treatment of insomnia and/or anxiety
- Major Unmet Medical Need – Large Addressable Market
  - Nearly ¼ of prescription opioid overdoses are related to alcohol
    - Risk of overdose 5 times higher in patients with alcohol problems
    - More than 1/3 of patients on long-term opioid therapy admit to drinking alcohol with their medication
  - Prescribers currently have no effective means of prevention
    - AROs already endorsed by key opinion leaders in pain medicine
    - Enthusiastic adoption rate expected
- Regulatory Advantages = Efficient Pathway to FDA Approval
  - Products utilize a combination of previously approved pharmaceutical ingredients
    - Enables an expedited ("505b2") application process that requires very little new clinical trial data, reducing program development costs and accelerating timelines dramatically as compared to the traditional ("505b1") approval pathway
    - SafeRX expects to submit its first New Drug Application (NDA) within 2 years of funding
  - Products address a designated Public Health Emergency
    - Cuts Agency review time to less than 6 months from NDA submission
- Capable Leadership – Ability to Optimize Return for Investors
  - Sophisticated, mission-driven founding team and board
  - Extensive industry experience and track record of success with life-science startups

MINIMUM INVESTMENT	MAXIMUM RAISE
$500	$5,000,000
TARGET MINIMUM	RAISED
$25,000	$0

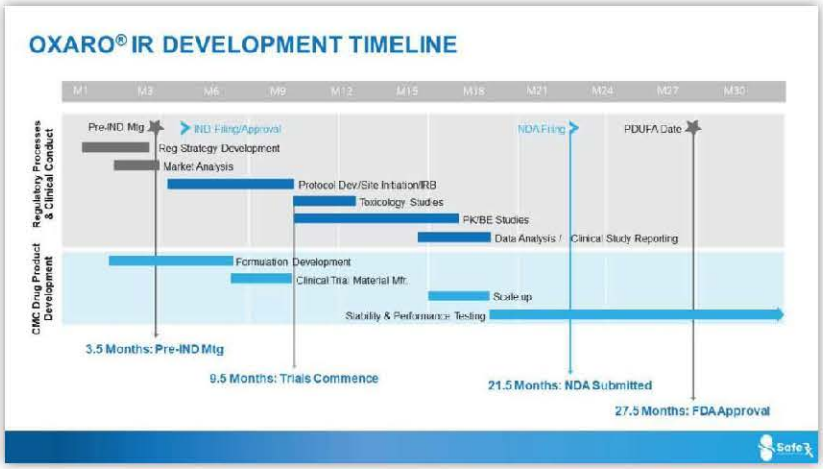
COMPANY PITCH DECK

Download SafeRx Pitch Deck

INNOVATIVE PRODUCT

The opioid crisis must be fought on multiple fronts, and our alcohol-resistant opioid products represent a paradigm-shifting solution to a major dimension of the crisis which has remained unaddressed by the pharmaceutical industry for decades. We believe this innovative platform of ARO products has the potential to drastically reduce the risk of death and hospitalization. The next step is FDA approval.

Although the overall budget for the two proposed inaugural ARO products is approximately $15 million, this will be divided into two rounds. The hypothetical investment return model assumes the company raises $5 million to get through the initial phase of the regulatory process and obtain investigational new drug (IND) designations and Agency approval for the OxARO® IR and MorhARO® IR clinical development plans. Given the pre-IND status of these programs, the current corporate valuation assumes only a 55% probability of achieving final FDA approval of the respective new drug applications. Once such clinical development programs are approved and IND designations are in place for these products, historically the probability of achieving NDA approvals increases dramatically. This is therefore expected to represent a major risk mitigation milestone, and we believe the company valuation will increase accordingly upon reaching it, at which point we intend to complete the fundraising process via a Series B round.



TEAM

MICHAEL PRESTI

FOUNDER-CEO

•MD and PhD (Neuroscience) from University of Florida

•NIH National Research Service Awardee

•Master's in Business Management from Warrington School, University of Florida

•Neurology residency and fellowship training at Mayo Clinic Rochester

•Diplomat of the ABPN and ABSM

•Inventor with multiple USPTO issued patents

RAY SISON

CHIEF PRODUCT OFFICER

•26+ yrs in pharmaceutical formulation dev, product launch and commercialization

•Created licensing, acquisition & commercialization opportunities for OptiNose, Lonza Group, Teva Pharma

•Expert in outsourced pharma development and virtual supply chain coordination

•Involved in product launches of Roxybond™ and Morphabond™, both ADF-labeled opioids

ADVISORS AND BOARD MEMBERS

JAMIE GROOMS

EXECUTIVE BOARD MEMBER

•Co-founded two highly successful life science companies: RTI Surgical, Inc. and AxoGen, Inc., both now publicly traded (NASDAQ: RTIX, AXGN)

•Former CEO of Florida Institute for Commercialization of Public Research

•Visionary and innovator in medical technology, regenerative medicine

•Successfully launched, managed, or advised numerous biotech startup companies

MARLO TAN WALPOLE

BOARD MEMBER

•Over two decades Product Development experience in Medical Device, HCT/Ps, Biologic, and Pharmaceutical industries

•Directed R&D at Aziz Thera Inc., AxoGen Inc. (NASDAQ: AXGN), RTI Surgical, Inc. (NASDAQ: RTIX) and other biotechnology companies

•Brings practical expertise especially for startup and small to mid-size companies

JIM PARRINO, MBA PHD

BOARD MEMBER

•Managing director and co-head of the M&A Buyside Advisory at Fifth Third Securities

•Managing director at Praxis Partners LLC

•Expert in corporate valuation, M&A, venture finance, entrepreneurship, corporate strategy, cross-border acquisitions

•CPA with 30+ years of operational, strategic and transactional M&A advisory experience

Terms

Minimum Investment

$ 500

Pre-money Valuation

$ 46,630,281.80

Maximum raise

$ 5M

Raised to date

$ 0

Target minimum

$ 25,000

USE OF PROCEEDS

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

DOCUMENTS

PDF

Form C

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DISCUSSION

Your email address will not be published. Required fields are marked *

Comment

Name*

Email*

Website

Save my name, email, and website in this browser for the next time I comment.

Post Comment

FAQs

1. Why invest in startups?

Crowdfunding allows investors to support startups and early-growth companies that they are passionate about. This is different from helping a company raise money on Kickstarter. With Regulation CF Offerings, you aren't buying products or merch. You are buying a piece of a company and helping it grow.

2. What types of securities can I buy on DirectCF?

The majority of offerings are common stock, though some companies may raise capital through convertible note, debt, and revenue share.

3. How much can I invest?

Individual investors are limited in the amounts they are allowed to invest in all Regulation Crowdfunding offerings over the course of a 12-month period: If either of an investor's annual income or net worth is less than $107,000, then the investor's investment limit $2,200, or 5 percent of the lesser of the investor's annual income or net worth, whichever is greater. If both an investors annual income and net worth are $107,000 or higher, then the investor's limit is 10 percent of their annual income or net worth, whichever is less. During the 12-month period, the aggregate amount of securities sold to an investor through all Regulation Crowdfunding offerings may not exceed $107,000, regardless of the investor's annual income or net worth.

4. How do I calculate my net worth?

Calculating net worth involves adding up all your assets and subtracting all your liabilities. The resulting sum is your net worth.

5. What are the tax implications of an equity crowdfunding investment?

We cannot give tax advice, and we encourage you to talk with your accountant or tax advisor before making an investment.

6. Who can invest in a Regulation CF Offering?

Individuals over 18 years of age can invest. Currently however, Canadian citizens are not able to invest in Regulation CF offerings listed with DirectCF.

7. What do I need to know about early-stage investing? Are these investments risky?

Companies on DirectCF are high risk opportunities and may not retain their value. Investing in startups and small businesses is inherently risky and standard company risk factors such as execution and strategy risk are often magnified at the early stages of a company. In the event that a company goes out of business, your ownership interest could lose all value. Furthermore, private investments in startup companies are illiquid instruments that typically take up to five and seven years (if ever) before an exit via acquisition, IPO, etc.

8. When will I get my investment back?

The companies listed on DirectCF are privately held companies, and their shares are not traded on a public stock exchange. As a result, the shares cannot be easily traded or sold. As an investor in a private company, you typically receive a return on your investment under the following two scenarios: The company gets acquired by another company. The company goes public (undergoes an initial public offering on the NASDAQ, NYSE, or another exchange). In those instances, you receive your pro-rata share of the distributions that occur. It can take 5-7 years (or longer) to see a distribution, as it takes years to build companies. In many cases, there will not be any distribution as a result of business failure. Dalmore Group, LLC does not make investment recommendations, and no communication, through this website or in any other medium should be construed as a recommendation for any security offered on or off this investment platform. Investments in private placements and start-up investments in particular are speculative and involve a high degree of risk, and those investors who cannot afford to lose their entire investment should not invest in start-ups. Companies seeking startup investments tend to be in earlier stages of development, and their business model, products and services may not yet be fully developed, operational or tested in the public marketplace. There is no guarantee that the stated valuation and other terms are accurate or in agreement with the market or industry valuations. Additionally, investors may receive restricted stock that may be subject to holding period requirements. The most sensible investment strategy for start-up investing may include a balanced portfolio of different start-ups. Start-ups should only be part of your overall investment portfolio. Investments in startups are highly illiquid and those investors who cannot hold an investment for the long term (at least 5-7 years) should not invest.

9. Can I sell my shares?

Shares sold via Regulation Crowdfunding offerings have a one-year lock up period before those shares become unrestricted and can be sold freely.

Exceptions to selling shares during the one-year lock up include:

- to the company that issued the securities;
- to an accredited investor;
- to a family member (defined as a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships.);
- in connection with your death or divorce or other similar circumstance;

10. What information does DirectCF collect from Issuers related to their offering?

The organization of the company Dalmore Group, LLC requires information that shows the issuer company has taken steps necessary to organize as a corporation or LLC in its state of organization, is in good standing, and that the securities being issued will be duly authorized and validly issued. The corporate structure and ownership Dalmore Group, LLC works with the issuer company to disclose its organizational structure, affiliated entities, and current capitalization. The people behind the company Dalmore Group, LLC helps the issuer company disclose who is behind the operations and strategy of the company, along with their previous related experience, and Bad Actor Reports to provide evidence that the company is not disqualified from proceeding with its offering. Information provided to investors Dalmore Group, LLC checks that the issuer company is providing clear disclosure of its financial situation, business origins, and operations, and legal authority to engage in its business activities. Investor information and terms of the offering Dalmore Group, LLC reviews for consistency each instance where the issuer company describes the offering terms, and identifies to investors how the issuer company reached its current valuation and will track and keep in touch with its security holders. Review of transaction documents Dalmore Group, LLC performs an independent review of transaction documents to check for red flags & conformance with stated terms. Business due diligence Dalmore Group, LLC conducts research and due diligence on each company before it is able to accept investments on the DirectCF platform. Dalmore Group, LLC will typically conduct over 30-40 hours of due diligence per opportunity, which requires the satisfactory completion of a detailed set of individual questions and data requests. Particular focus is paid to the following issues throughout the due diligence process: Problem or inefficiency being addressed Product / service overview, stage of development and anticipated milestones Demonstrated traction (e.g. revenue, pre-sales, purchase orders, signed contracts, media coverage, awards, etc.) Data to support claims made in marketing materials (e.g. user / customer metrics, signed contracts and agreements, product demonstrations, etc.) Growth

strategy Employees and advisors (including ownership structure) Addressable market (e.g. size, growth, penetration, etc.) Competitive landscape and industry dynamics Exit opportunities Intellectual property Historical financials Financial projections (including error-checking, evaluation of key assumptions and reconciliation to stated growth plan) Reference checks (e.g. previous investors, advisors, etc.) Investment overview (including determination of key terms, uses of funds, and current and previous investors) The findings of the foregoing review are presented to Dalmore Group, LLC, which may approve, reject, or require additional information for the offering. Upon approval and following the onboarding process, an offering can begin accepting investments online. General considerations Notwithstanding the foregoing, these investments are illiquid, risky and speculative and you may lose your entire investment. The foregoing summarizes our standard process. However, each diligence review is tailored to the nature of the company, so the aforementioned process is not the exact process for every issuer. Completing the vetting process does NOT guarantee that the company has no outstanding issues or that problems will not arise in the future. While the foregoing process is designed to identify material issues, there is no guarantee that there will not be errors, omissions, or oversights in the due diligence process or in the work of third-party vendors utilized by Dalmore Group, LLC and DirectCF. Each investor must conduct their own independent review of documentation and perform their own independent due diligence and should ask for any further information required to make an investment decision.

▲ 11. What happens if a company does not reach their funding goal?

If a company does not reach their minimum funding goal, all funds will be returned to the investors after the closing of their offering.

▲ 12. How can I learn more about a Company's offering?

All available financial information can be found on the offering pages for the company's Regulation Crowdfunding offering.

▲ 13. What if I change my mind about investing?

You may cancel your investment at any time, for any reason until 48 hours prior to a closing occurring. If you have already funded your investment and your funds are in escrow, your funds will be promptly refunded to you upon cancellation. To submit a request to cancel your investment please email support@directcf.com.

▲ 14. How do I contact someone at DirectCF?

if you have questions that have not been answered in the FAQ, please email our Investor Support Team at Investor@directCF.com