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FOR RELEASE

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PFD Management Opportunity Fund 3001, LLC Announces:

Announced today by Robert Pryke PFD Capital Partners, LLC, Director and Fund manager for PFD Management Opportunity Fund 3001, LLC, additional points of interest related to its casdermaRx portfolio project.

cassdermaRx Q123 Development Report

PFD Capital Partners, LLC is releasing the following information in relation to the progress of one of the medical technology companies within the **PFD Management Opportunity Fund 3001, LLC. cassdermaRx** has been in the development of an innovative solution for individuals with chronic wound conditions that have been resistant to most traditional treatment methods available today.

As has been discussed in previous releases, **cassdermaRx** is the developer of an innovative prescription topical gel that supports the rapid regeneration of tissue for atrophic recalcitrant wounds. The gel is based on a patented formulation that uses a serum-free, nutrient-rich medium to the wound site along with a non-steroidal anabolic hormone to stimulate and support the growth of connective tissue originating from a wound bed and its peripheral walls. The gel has been found to be effective in reducing the healing time on a broad spectrum of wound types including diabetic ulcers, pressure ulcers, burns, and surgical wounds. The formulation has even been found to be effective in treating persistent long-term wounds where other current methods of regeneration have been unsuccessful.

As such, the **cassderma Rx Wound Healing Hydrogel** represents a novel disruptive solution in the topical wound care market sector. The product's patented formulation is the first to bring active nutrients in a cell culture medium (CCM) along with a naturally occurring cell growth hormone that together is designed to not just protect a wound site while healing occurs but to promote and accelerate healthy cell and connective tissue repair in order for the cure to occur.

As the company approaches the end of Q123 it has announced several milestone junctures it has met as it continues its path forward to commercialization.

Formulation Refinement

cassdermaRx continues to refine its Wound Healing Hydrogel formulation to determine the best balance of its cell growth hormone, Insulin, which stimulates and supports the growth of connective tissue components originating from the wound bed and its peripheral walls, its active nutrient CCM, which provides moisture to the wound site and nutrients required for cell proliferation and the growth of the granulation tissue into the wound space, and its excipient gel components that provide viscosity and elasticity that assist in maintaining residence of the product at the wound site.

TIOGA RESEARCH

Skin Delivery Innovations

cassdermaRx's strategic partnering with Tioga Research enables to have the expertise of not only a top formulation company in the topical drug product catagiry but also to leverage the experience of it parent compay Encube Ethicals is the world's largest single-site manufacturing facility for topical pharmaceutical products.

Encube

The company has developed a strategic relationship with Tioga Research in furthering its formulation efforts. Tioga Research is a 'pure play' contract research organization ("CRO") specializing in the research and development of topical drug products, transdermal drug products, prestige cosmetics, and personal care products as it pertains to moving them from concept to the point of Investigational New Drug (IND) application. Tioga Research is noted for its world-leading capabilities in formulation innovation and skin delivery and permeation screening abilities. Tioga Research's parent company, Encube Ethicals, operates the world's largest single-site manufacturing facility for topical pharmaceutical products. When a formulation program graduates successfully from Tioga Research, a client has the option to benefit from Encube's capabilities to progress the program into manufacturing through all phases of clinical trials and to a full commercial scale.

cassdermaRx has been able to refine its formulation down to five principal candidates and is currently finishing its internal review process to determine which of these will be advanced for its initial pre-clinical study which is anticipated to start in Q2 of this year.

The five formulations all have been shown to be effective in providing chronic wound-care benefits and are now being evaluated to determine the best viability as it applies to three of the important criteria related to end-use application; viscosity, shelf-life, and reproducibility.

cassdermaRx has refined its formulation for its Wound Healing Hydrogel down to five candidates for its initial Pre-Clinical Research study to be done in Q2 of this year.

- ***Viscosity*** – the viscosity of any topical agent is important for two critical purposes. The first is the product's ability to maintain residency at the point of application for the time period necessary

for the effectiveness of the ingredients to be fully realized. Several factors determine this such as if the application will be in an open-air environment or under a wound dressing, if the area of application will be stationary or positionally active, and if exterior factors such as clothing and activity can impact the product's action. The second purpose that viscosity serves is in determining the time release of the ingredients to the application site. A thinner viscosity, such as an alcohol-based medication is best suited for the delivery of rapidly absorbed agents such as hormonal medication, whereas a thicker viscosity is important where the active agent needs to remain in contact with the application area for an extended period in order to provide a slow, metronomic release to provide the effect desired.

- ***Shelf-life*** - the shelf-life of a product reflects the time period during which the product is known to remain stable, which means it retains its strength, quality, and purity when it is stored according to its labeled storage conditions. As it pertains to topical formulations, shelf-life is important when calculating not only the average amount per use times times number of uses to effect benefit but also the calculations used in determining product volume size, packaging type, storage requirements as well as manufacture and distribution processes. FDA regulations require drug applicants to provide stability testing data with a proposed expiration date and storage conditions when they submit an application for FDA approval of their drug. This testing is designed to provide confidence that the product will meet the applicable standards of strength, quality, and purity throughout its shelf-life. The FDA verifies that an applicant's proposed expiration date is supported by appropriate studies that the applicant has conducted.

- ***Manufacture Scalability*** - The ability to move any product to scale to meet market demand is a critical factor in determining the long-term viability of a product. Factors such as the availability and cost of ingredients, ability to manufacture at larger volumes, reliability of process partners, and ability to scale in either direction or to add product variables such as need-specific formulations, active ingredient percentages, and viscosity variations in the case of topical products, all can have an impact on both FDA approval and the IP owner's decision to move to market.

Mike Sweeting
Vice-President of Regulatory

cassdermaRx has almost completed its viscosity determination and by extension, this will greatly determine the parameters around the shelf-life information it needs to present to the FDA. As to the manufacture scalability, the company has performed extensive market analysis research, under the direction of Mike Sweeting, **cassdermaRx's** Vice-President of Regulatory, to ascertain its strategy to meet the anticipated market penetration once it is able to achieve FDA approval. Mike has over 30 years of experience in the pharmaceutical product development field. He has worked with large companies such as Sanofi, a multinational firm focused on the research and development and the manufacturing and marketing of pharmacological products, principally in the prescription and OTC market, and Mallinckrodt Pharmaceuticals, a US manufacturer of specialty pharmaceuticals, generic drugs, and imaging agents. Mike has a unique ability to formulate a company's strategic direction that is based on analytics and an understanding of the markets, then work to build out the organizational talent to not only achieve goals but to exceed them.

Investigating
an Investigational New Drug

Obtaining an Investigational New Drug (ID) status from the FDA allows the developer of a new pharmaceutical product to begin limited human clinical trials in order to gather the validation data to move the drug into an approved drug status for full marketing of the drug to the public.

To file for an IND, the developer must submit documentation detailing its proposed study, provide information about the investigator and study site, and certify that the study is registered in the national database of clinical trials. If the IND is approved, the study may begin 30 days after the FDA acknowledges receipt and assigns an IND.

By filing for an IND, the developer immediately invokes a number of specific regulatory requirements beyond those mandated for the protection of human subjects in clinical trials. These regulatory requirements for drug studies address the safety and efficacy issues unique to the use of pharmaceuticals in the clinical research setting.

With the IND the developer is able in conjugation with an Institutional Review Board (IRB) Sponsor to conduct its studies at approved medical sites, such as hospitals, research, and clinical trial facilities, per an approved protocol program that outlines the studies purpose, anticipated results, as well as the cohort size, validation methods and time frame for study completion and follow-up.

Pre-Clinical Study

With the initial formulation research complete, **cassdermaRx** is now preparing for its first Pre-Clinical In-Vivo Animal Study in order to procure the data and validation information necessary for its FDA Pre-IND evaluation. As has been noted in prior releases, **cassdermaRx** is seeking FDA IND status for its Wound Healing Hydrogel to begin its Phase One human clinical trials. In order to obtain an IND, a company must first submit an application that shows that milestones have been met to warrant an IND review. These milestones are encapsulated in three areas of inquiry:

- Animal Pharmacology and Toxicology Studies - Pre-Clinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans including any previous experience with the drug in humans both in the US or in foreign markets.
- Manufacturing Information - Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.
- Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators--professionals (generally physicians) who oversee the administration of the experimental compound--to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain a review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations.

cassdermaRx has already begun talks and Request For Proposal (RFP) inquiries with several qualified labs to partner with in order to perform the Pre-Clinical In-Vivo Animal Study for the IND submission. The labs all have experience in biotech and pharmaceutical company trials as they apply to obtaining regulatory approval data, and analytical research to streamline and simplify the approval process for new product formulation approval.

cassdermaRx anticipates having all its Pre-Clinical Study data, study protocols, and lab selections in place by Q2 of this year and anticipates the start of the study shortly thereafter. Upon the anticipated successful completion of the study, the company will then prepare its FDA IND application submission with a Pre-IND review by the FDA to follow shortly thereafter. During the Pre-IND review, the FDA will determine that all the submission requirements have been met and will advise on any additional materials or data that will be needed before the final IND review is scheduled. The average time track from submission to Pre-IND, to IND review to IND approval, is three to six months, at which point the company can immediately move to its Phase One Clinical Trial.

The Path Forward

In a previous release, a **US Health and Human Services Department 2022** report was cited which showed that the FDA understands that innovative product development is essential to addressing the unmet medical need of non-healing chronic wounds. To that end, the FDA has put renewed focus on efforts to address identified barriers to product development for non-healing chronic wounds. In collaboration with key wound healing stakeholders including academia, professional associations, patient groups, reimbursement organizations, and industry, the FDA intends to help advance product development for non-healing chronic wounds for the ultimate betterment of patients. With this in mind and other market factors such as the announcement by Eli Lilly to cut insulin prices by 70%, **cassdermaRx** feels it is in a positive nexus of need, solution, and market in order to achieve its commercialization goals.

PFD Capital Partners, Inc.

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PFD MOF 3001 Management Opportunity Fund

A medical account receivables and medical technology finance fund offering a fixed rate return with additional equity participation in targeted new medical technology opportunities.

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