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FOR RELEASE

January 18, 2023 | News

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 portfolio project, RAD/iKnee.

PFDiOI RADiKnee

Lake Forest, CA: PFD/iOrthopedics Inc. (PFD/iOI) has updated its development status on the **Resilient Arthroplasty Device – iKnee.**

Our next big event is one step closer…the 7-year wait is finally coming to fruition!! The delivery of our Arburg Freeformer 300-3X arrived on **Monday, January 16th at our PFD/ iOI Los Angeles Facility.**

The **Arburg** Freeformer 300-3X is revolutionary regarding their proprietary technology in that it is the only 3D printer in the world that can print our revolutionary **iKnee** using the Polymer **Quadrathane** from **Biomerics**. This unique 3D printer has the ability the utilize and upload the test design enhancements by our engineering team at **EnginuityWorks**. This updated initial implant design, has been reviewed by **Dr. Thomas Grotz and Dr. Christopher Woodson,** will be sent off to **PFD/iOI** for 3D Print and initial **Proof of Concept (POC)** with **First in Human (FIH)** implant and the launch of our **iKnee Comfort Study.**

The **Arburg** Freeformer 300-3X will be placed in our **PFD/iOI RAD/iKnee** Printing **Clean Room**.

This room contains 3 phase electrical with compressed air and Oxygen and Nitrogen. The lab consists of three different spaces that allow the company the ability to test prototype designs, perform quality control checks, and establish operational and test protocols while gathering the important analytical and comparative clinical data needed to further its regulatory approval strategy.

One of the spaces comprises a 500sq/ft ISO-7 clean room capable of maintaining an air quality of less than 10k particulates per cubic foot with an advanced positive air HEPA filtration system. This room allows the engineering team to perform any biological studies and electrical fabrication work that require a high degree of air purification to prevent contamination of a process.

A second 500 sq/ft ISO 9 clean room is set up to allow less critical mechanical engineering and software/firmware testing to be done.

The last space comprises an 800 sq/ft operating suite.

A **cleanroom** or **clean room** is an engineered space, which maintains a very low concentration of airborne particulates. It is well isolated, well-controlled from contamination, and actively cleansed. Such rooms are commonly needed for scientific research, and in industrial production for all nanoscale processes, such as semiconductor manufacturing. A cleanroom is designed to keep everything from dust to airborne organisms, or vaporized particles, away from it, and so from whatever material is being handled inside it.

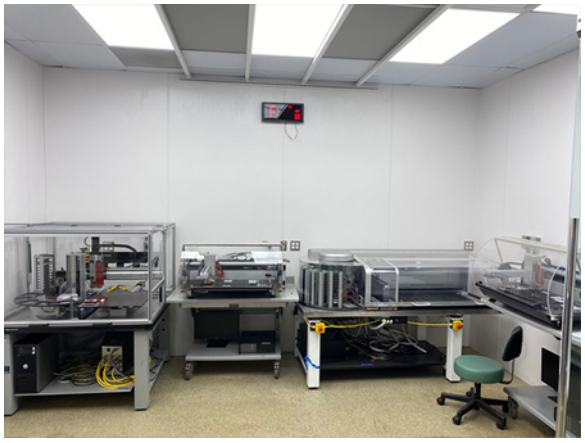
Exterior view of the PFD Affiliated facility located in Inglewood, CA. This building is a Dept. of Defense restricted facility which also houses one of the few privately funded and FDA certified animal testing surgery centers in California.

This facility was where Magnetecs created its CGCI mapping and guidance system for surgical tools, Sensor Kinesis developed its sensor technology program, and where PFD/iOI will print the Resilient Arthroplasty Device (RAD) for iKnee.

Security exterior equipment entry shipping and receiving point.

Inside facility looking out loading bay door

Clean room entrance where the Arburg Freeformer 300 3X #D printer will be housed and operated.

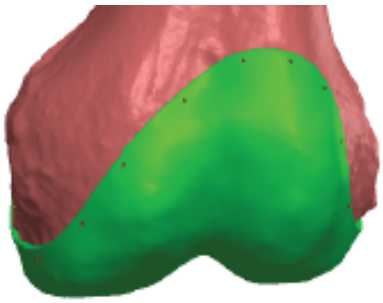


This is a shot of the actual clean room.

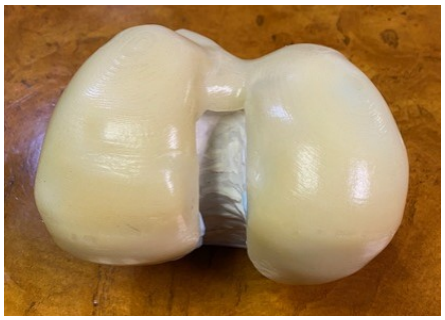
The **PFD/iOrthopedics Inc Resilient Arthroplasty Device (RAD)**, and its first product candidate the iKnee, has been **IRB IDE** authorized for human use in the first **10,000** qualified patients.

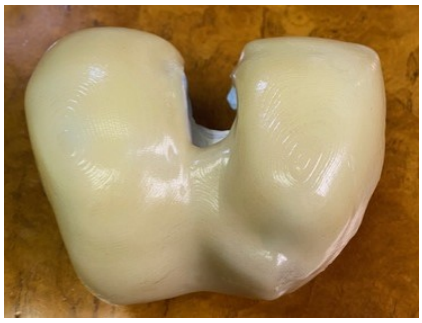
Dr. Christopher Woodson is the **Principal Investigator** in the study. The device bridges the existing gap between non-invasive and totally invasive, ablative surgical procedures.

The initial implant will also undergo the post-production smoothing process. The implant (prototype) smoothing process occurs after the prototype is transferred from the 3D Printer and the exterior surface needs some additional refining. The smoothing process developed by **AM Technologies** revolutionized specifically for **RAD - iKnee**, uses a green plant-based consumable solution on the **iKnee Quadrathane PU** material for optimum and exceptional results.



The images above show the **iKnee** prototype model with the perimeter borders being drawn out on the digitally prepared post sculptured processed knee of our first human candidate. The technology for the pre-surgical sculpturing was developed by **Materialise** and uses their **Mimics** software applied to CT manufacturers workstations. The images also show the **iKnee** initial drawings on the candidate's distal femur and the actual **STL File** image to be used for 3D Printing.





About PFD/iOrthopedics. Inc.

The **PFD/iOrthopedics INC (PFD/iOI), Resilient Arthroplasty Device (RAD)**, and its first product candidate the **iKnee**, has been **IRB IDE** authorized for human use in the first 10,000 qualified patients.

PFD/iOI is introducing a 21st Century, personalized, patient driven, novel and highly disruptive restorative, joint salvage outpatient approach.

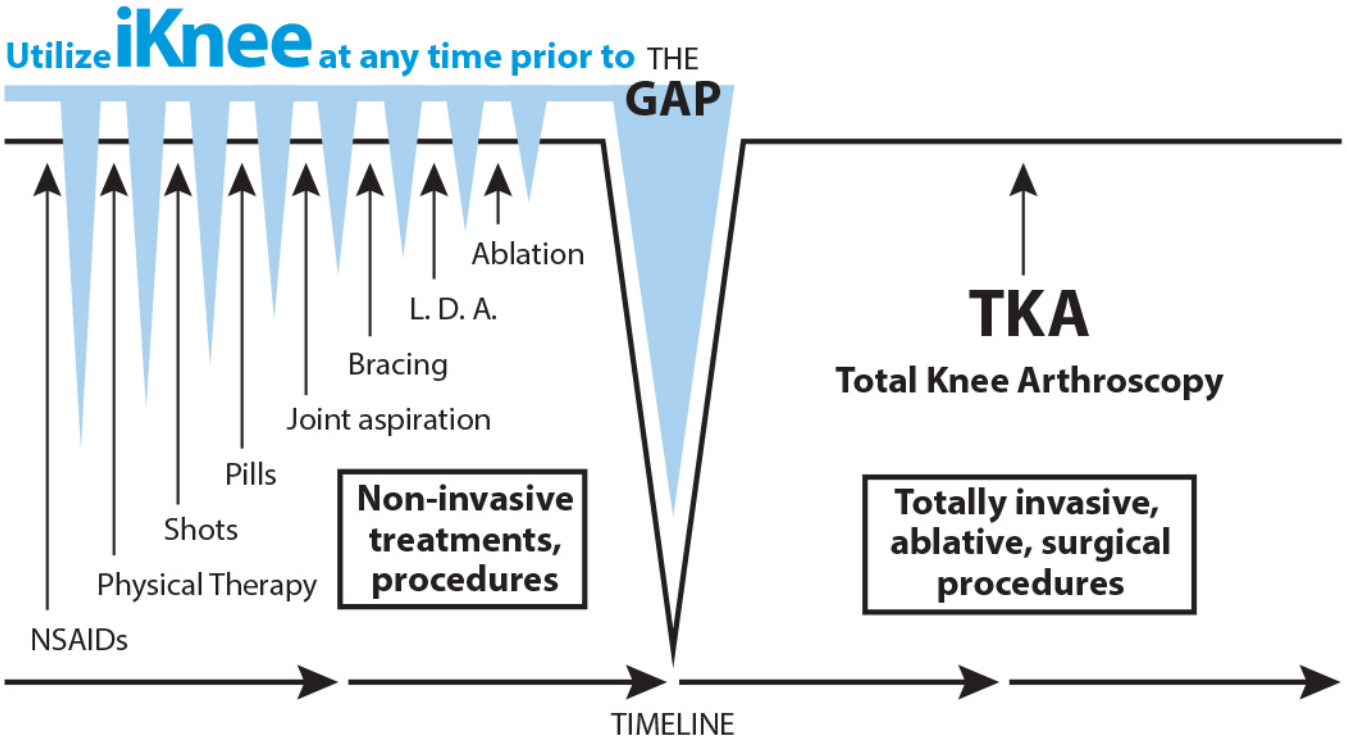
It is an effective solution to fill the gaping, costly, inefficient, and non-therapeutic void between pills, shots, bracings, physical therapies, and the limiting of daily activity for patients suffering from osteoarthritis.

This additional interventional option may potentially eliminate or at least delay the much more dramatic, life altering and invasive surgical replacement of joints with a simple outpatient procedure.

The intent was that this principle would be used in all mammalian joints; think animal and human to include the knee, hip, shoulder, etc throughout all the long bone interfaces (appendicular skeleton).

The Resilient Arthroplasty Device (RAD), referred to as the **iKnee**, is a patented implantable medical device by which patients presenting with osteoarthritis will find pain relief through the padding, cushioning, and protecting of the damaged joint surfaces.

The iKnee will change the pain profile by covering the dominant surface of the damaged joints very much like the original cartilage.



Strategic Alliances

The following is provided for purposes of giving the reader deeper appreciation of the strategic alliances involved with bringing the PFD/iOI technology to commercialization.

QUADRATHANE

Quadrathane™ ARC is a family of aromatic polycarbonate-based thermoplastic polyurethane. It offers superior biocompatibility, superior chemical resistance, and oxidative stability for use in long term body implantable applications. It is naturally clear, hemocompatible, and is USP Class VI and ISO-10993 compliant. Quadrathane™ ARC is used across a wide range of medical applications including chronic indwelling catheters, feeding catheters, pacemaker leads, coatings, orthopedics, and other applications where superior chemical resistance is required. The iKnee will use Quadrathane ARC 70 A.

Mimics Innovation Suite

In furtherance to complete comprehensive personalized medicine, PFD/iOI has utilized Materialise, as the industry-standard medical image-based engineering software and service, MIS puts us in control with the most advanced tools to support our mission to improve patient care. Medical image data thus serves as a powerful basis for engineers and researchers striving for solutions that will lead to safer and more predictable personalized patient outcomes.
The Mimics Innovation Suite was designed to make using medical image data for engineering purposes as easy and rewarding as possible.

Production of a 3D Printed Part Doesn't Stop at the Printer.

Post-processing is required to finish 3D printed parts for end-use. Traditional methods are slow, difficult to predict consistency, and can account for up to 60% of the part cost.

PostPro, developed by AMT, is a digital post-production technology platform that automates the manual and costly steps associated with legacy 1.0 'low volume and prototyping' post-processing and enables functional 'high-volume end-use parts' production from 3D printers.

PostPro allows companies to leverage the benefits of additive manufacturing at scale, by providing an order of magnitude improvement in part throughput, performance, quality, cost, and safety.

Benefits of vapor smoothing to seal surfaces for easier cleaning and sterilization are a game changer for the medical and food industries.

Vapor smoothing surfaces prevents liquid absorption, allowing for development of new applications in numerous industries. Vapor smoothing the parts in preparation for surface coating and dying will significantly reduce the time needed to get perfect results.

Repeatability and consistency of performance results directly enable scaling up of manufacturing processes and volumes.

Arburg Plastic Freeforming

ARBURG Plastic Freeforming (APF) technology uses qualified standard granulates employed in injection molding technique. Using the material jetting method, these granulate are melted and discharged to fabricate thermoplastic parts.

Freeformer 300-3X is **an industrial 3D printer** produced by ARBURGadditive. ARBURGadditive is a 3D printer manufacturer based in Germany.

The Arburg Freeformer 300-3X will be placed in our **PFD/iOI RAD** printing **Clean Room**. This room contains 3 phase electrical with compressed air and Oxygen and Nitrogen. The lab consists of three different spaces that allow the company the ability to test prototype designs, perform quality control checks, and establish operational and test protocols while gathering the important analytical and comparative clinical data needed to further its regulatory approval strategy.

STL File

The STL file format is the most used file format for 3D printing. When used in conjunction with a 3D slicer, it allows a computer to communicate with 3D printer hardware.

The STL file format has been adopted and supported by many CAD software packages. Today it is widely used for rapid prototyping, 3D printing, and computer-aided manufacturing.

Enginuity Works

Enginuity Works provides our engineering consultation for the full range of product development services, Industrial Design, Mechanical Engineering, Electrical Engineering, Prototyping, R&D, and Manufacturing Management. Their approach identifies the best-fit of our own expertise and capabilities with their engineering team.

The following section is provided as a very basic tutorial on regulatory path and some of the terms, processes, and programs that new medical technologies must navigate to become commercial in the United States.

Under FDA regulations, an Institutional Review Board is a group that has been formally designated to review and monitor biomedical research involving human subjects.

In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research.

This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

PFD/iOrthopedics Inc have been granted a very favorable multi-site IRB for 2022-2023

Institutional Review Board (IRB) Services Solutions to Safeguard Trial Participants

ADVARRA

Regardless of a project's scope, therapeutic niche, or number of investigators, Advarra is our partner in the conduct of efficient, responsible research. Objectivity and concern for participant well-being drive all review decisions.

IKNEE COMFORT STUDY

iKnee brief study description: iKnee seeks to provide temporary comfort and improved function for patients awaiting total knee replacement arthroplasty (TKA). Reasons to delay a TKA include but are not limited to need for weight loss, wound infection healing, implant availability, and required medical or psychological patient preparations. iKnee use determinations are made between the patient and caretaker. The subject population is individuals with refractory disabling knee pain who failed other conservative measures and are on track for TKA. The iKnee is to provide comfort, it is not intended to treat a disease, or underlying cause leading to TKA.

Objective: To study iKnee efficacy on quality of life and activities of daily living in patients awaiting TKA. The data will be used to improve possible design to enhance patient comfort.

Procedure: A rolled polymer is inserted through a small parapatellar incision then expanded to fit and pad the distal femur, providing a stable cushion made of medical polymers used safely and reliably for decades. The procedure is expected to take about 30 minutes, involves an incision of 2-3 cm and subcutaneous tissue into the joint capsule, an incision less than one cm in depth. Then the iKnee device is inserted into the knee capsule. No muscle, tendons, or ligaments are cut.

Study Rationale: Total Knee Arthroplasty (TKA) has become one of the leading operations for senior citizens, both in cost and frequency. When a patient has a disabling knee condition limiting mobility and quality of life there is only one medical option, TKA. The TKA operation is a significant procedure, involving the removal of the bottom of the femur, top of the tibia, and part of the patella to make space for the artificial metal and polyethylene prosthesis.

The study is designed to increase patient quality of life, functionality, and comfort while they await the knee replacement operation (TKA). The iKnee procedure poses almost no medical risk to the patient, either as a procedure or as a risk to the patient knee as the decision has already been made to remove the joint.

Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study is initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study and;
- required records and reports.

First In Human (FIH)

A type of clinical trial in which a new drug, procedure, or treatment is tested in humans for the first time. Also called first-in-human study.

The following is provided as additional generic tutorial relative to the regulatory pathway for commercialization.

NON-SIGNIFICANT RISK

The FDA does not regulate NSR, "Non-Significant Risk.

The Sponsor has the responsibility of making the SR or NSR risk determination, and may utilize the services of an IRB, but not required.

The RAD - iKnee device does not refer to any disease. We are implanting this minimally invasive device for patient "quality of life "issues while they await a full TKA. This may be for comfort, mobility, or many other non-disease related terms.

What is a Non-significant Risk Device Study?

NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b).

An IRB's NSR determination is important because the IRB serves as the FDA's surrogate for review, approval, and continuing review of the NSR device studies.

An NSR device study may start at the institution as soon as the IRB reviews and approves the study and without prior approval by FDA.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 812 -- INVESTIGATIONAL DEVICE EXEMPTIONS

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.2

FDA Pathways

FDA designation of the **iKnee** as a **Non-Significant Risk** (NSR) Device.

Pathways for commercialization to be determined based on commercialization path of purchaser of IP.

7 FDA Pathways to Bring a Medical Device to Market

1.) Premarket Notification 510(k)
The **Premarket Notification 510(k)** pathway is the most common route taken when launching a medical device. Almost all Class II devices and certain Class I devices will require a 510(k).

The purpose of a **510(k) submission** is to provide the FDA with documented evidence showing that a medical device is substantially equivalent in terms of safety and effectiveness to a predicate device.

A predicate device is one that is already legally marketed and shares the same intended use and technological characteristics as the new device. The requirement is to compare the new device with the predicate by summarizing information from the design controls process, such as design features and verification testing.

The FDA typically processes 510(k) applications in 30-90 days. Depending on the robustness of the initial application, there may be a period of back-and-forth discussions, of which can delay the process. It is important to plan and provide all appropriate documentation at the time of initial submission.

2.) Premarket Approval (PMA)
Class III devices, and any device that cannot provide substantial equivalence to a Class I or Class II device through the 510(k) process, must use the **Premarket Approval (PMA)** pathway.

The PMA process is the most involved as scientific evidence, typically in the form of a clinical trial, is needed to prove the safety and effectiveness of the new device.

The FDA will either approve or reject the application within 180 days. The different steps of the review process include:

1. FDA staff will determine completeness through an administrative and limited scientific review
2. FDA staff will conduct an in-depth scientific, regulatory, and Quality System review
3. An advisory committee will review and offer any recommendations.
4. Any final deliberations will occur, and the FDA will document and notify the applicant of their final decision.

Although the premarket approval process sounds intimidating, it is the right option for a high risk, Class III device.

3.) De Novo
If the applicant is developing a lower risk, "novel" device and struggling to find a predicate, the De Novo pathway might be the best option.

The **De Novo** pathway has been around since 1997 but many people do not know about it since it is not very commonly used. Companies that do not qualify for 510(k) clearance, since they cannot provide substantial equivalence to a device on the market, should learn more about the De Novo pathway.

Since comparison to a predicate is not needed, companies have a "blank canvas" when it comes to labeling and can set a standard that may give them a competitive advantage over others. One of the key things to remember about the De Novo pathway is that the device must present low to moderate risk through a robust risk mitigation strategy.

4.) Humanitarian Device Exemption (HDE)

The **Humanitarian Device Exemption (HDE)** pathway is for devices that are intended to treat or diagnose conditions or diseases that affect small or rare populations.

This pathway involves a two-step process. The FDA must grant a Humanitarian Use Device (HUD) exemption and the device company must then submit an HDE application to the appropriate review center.

Another important requirement is that there cannot be another comparable device on the market that shares the same intended use. The FDA will consider the following when determining if there are comparable devices on the market:

- The device's indications for use and technological characteristics.
- The patient population to be treated or diagnosed with the device.
- Whether the device meets the needs of the identified patient population.

Part of the rationale for providing this pathway is there may not be a large enough patient population with clinical data to satisfy regular FDA requirements of safety and efficacy. Since these devices may be very crucial to patients with rare conditions, the FDA put it in place to do a proper review to determine if the device can be sold.

5.) Custom Device Exemption (CDE)

Is the company developing a custom device for a specific patient? If so, the device falls under the **Custom Device Exemption (CDE)** pathway and must meet a very narrow set of criteria.

The device must be created or modified to comply with the order of an individual physician or dentist, typically in the form of a prescription. Not only must the clinician order the device, but it must also be used in the normal course of the professional practice of that physician or dentist.

The product should be specifically designed to treat a unique pathology or physiological condition that no other device is domestically available to treat. It must be assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of the patient.

The FDA even states that companies are limited to no more than 5 units per year of a particular device type.

CDE devices are exempt from PMA or 510(k) submission process, but the company still needs to comply with the following regulations:

- Design Controls (21 CFR Part 820)
- Medical Device Reporting (21 CFR Part 803)
- Labeling (21 CFR Part 801)
- Corrections and Removals (21 CFR Part 806)
- Registration and Listing (21 CFR Part 807)

6.) Expanded Access Program (EAP)
The **Expanded Access Program**, often referred to as the compassionate use or emergency use provision, is fairly self-explanatory.

It allows an investigational device to be used, outside of a clinical trial, in situations where a seriously ill patient has few if any alternatives.

Although there are often ethical considerations, it may be appropriate to evaluate this option to get early feasibility data for high-risk devices, especially when suitable animal models are unavailable. Like the HDE, this data could then be used to expand the label in the future.

Expanded access may be an appropriate pathway for you to choose when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

7.) Product Development Protocol (PDP)
The **Product Development Protocol (PDP)** is a subset of the PMA process that allows for another pathway for companies with devices in which the technology is well established in the industry.

This pathway allows the company to come to an early agreement with the FDA about how safety and effectiveness of the device will be shown. The two parties are essentially creating a contract that describes design and development activities, including the outputs of these activities, and acceptance criteria for these outputs.

The company can follow the plan on their own time and report back to the FDA on the agreed upon milestones. At the end of the process, the company is considered to have "completed" a PDP, which gives them an "approved" PMA.

A managing sponsor of fundraising efforts for the affiliated companies of the PFD family of companies, PFD Capital Partners, INC provides capital formulation, management, and portfolio admin. services.

An operational Class A member and manager to the PFD Family Private Equity programs.

PFD Management, LLC is a vendor to the PFD family of private funds, specializing in sourcing, diligence, underwriting, auditing, packaging, servicing, billing/collecting and portfolio administration of account receivables.

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

SAFE HARBOR DECLARATION

THE STATEMENTS, PROJECTIONS AND ESTIMATES OF FUTURE PERFORMANCE OF THE COMPANY OR VARIOUS ELEMENTS OF THE COMPANY'S BUSINESS CONTAINED IN THIS MEMORANDUM THAT ARE NOT HISTORICAL FACTS ARE FORWARD-LOOKING STATEMENTS. INVESTORS SHOULD EXPECT THAT ANTICIPATED EVENTS AND CIRCUMSTANCES MAY NOT OCCUR, THAT UNANTICIPATED EVENTS AND CIRCUMSTANCES WILL OCCUR, AND THAT ACTUAL RESULTS WILL LIKELY VARY FROM THE FORWARD-LOOKING STATEMENTS. INVESTORS SHOULD BE AWARE THAT A NUMBER OF FACTORS COULD CAUSE THE FORWARD-LOOKING STATEMENTS OR PROJECTIONS CONTAINED IN THIS MEMORANDUM OR OTHERWISE MADE BY OR ON BEHALF OF THE COMPANY TO BE INCORRECT OR TO DIFFER MATERIALLY FROM ACTUAL RESULTS. SUCH FACTORS MAY INCLUDE, WITHOUT LIMITATION, (i) THE ABILITY OF THE COMPANY TO COMPLETE THE DEVELOPMENT OF ITS PRODUCTS IN A TIMELY MANNER, (ii) THE DEMAND FOR AND TIMING OF DEMAND FOR SUCH PRODUCTS, (iii) COMPETITION FROM OTHER PRODUCTS AND COMPANIES, (iv) THE RESULTS OF THE COMPANY'S SAFETY AND EFFICACY STUDIES, (v) THE RESULTS OF THE REGULATORY APPROVAL PROCESS, (vi) THE COMPANY'S SALES AND MARKETING CAPABILITIES, (vii) THE COMPANY'S ABILITY TO SELL ITS PRODUCTS PROFITABLY, (viii) THE ABILITY OF THE COMPANY'S THIRD-PARTY SUPPLIERS TO PROVIDE PRODUCTS AND SERVICES IN A RELIABLE MANNER; (ix) AVAILABILITY OF ADEQUATE DEBT AND EQUITY FINANCING, AND (x) GENERAL BUSINESS AND ECONOMIC CONDITIONS. THESE IMPORTANT FACTORS AND CERTAIN OTHER FACTORS THAT MIGHT AFFECT THE COMPANY'S FINANCIAL AND BUSINESS RESULTS ARE DISCUSSED IN THIS MEMORANDUM UNDER "RISK FACTORS." THERE CAN BE NO ASSURANCE THAT THE COMPANY WILL BE ABLE TO ANTICIPATE, RESPOND TO OR ADAPT TO CHANGES IN ANY FACTORS AFFECTING THE COMPANY'S BUSINESS AND FINANCIAL RESULTS.