PRESENTERS OF THE 2022 CANADA-ISRAEL CARDIOVASCULAR INNOVATION FORUM

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Kashif Khan	PLAKK Inc. (Canada)	Saving Lives One Scan at a Time: An Artificial Intelligence-Powered Ultrasound Analysis Tool to Characterize and Detect Unstable Plaques	kashif.khan@plakk-ai.com
Bradley Strauss	RBY Medical (Canada)	Angioplasty Support Sleeve for Peripheral Arterial Interventions	Bradley.strauss@sunnybrook.ca
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INNOVATION SUMMARIES

Arik Eisenkraft, Biobeat Technologies Ltd.

Innovation: Remote Cardiac Rehabilitation Using an Advanced Noninvasive Wireless Wearable monitoring platform in High-Risk Heart Failure Patients

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Biobeat is a young med-tech company with unique health-AI capabilities in the remote patient monitoring (RPM) space. The company's cloud-based RPM health-AI platform includes a disposable, wireless, wearable, non-invasive short-term chest monitor, and a long-term wrist monitor. Both monitors utilize a photoplethysmography-based (PPG) sensor, which continuously provides accurate patient readings of 13 physiological and health parameters,

including cardiac output, cuff-less blood pressure, pulse rate, respiratory rate, blood oxygen saturation, temperature, stroke volume, systemic vascular resistance, one lead ECG (only in the chest-monitor), and more. The automatically-generated data are being analyzed using proprietary big-data and machine learning tools, leading to advanced clinical insights that help both healthcare providers and health policy leaders, in both individual adjustment of treatment and in national health policy guidance (e.g., approach to handle influenza and other infectious diseases). The platform includes an Early Warning Score system (based on NEWS), providing timely alerts of the potential of patient deterioration, providing a valuable benefit as an important aid to the nursing duties, especially during current times of workforce challenges. The platform is HIPAA and GDPR compliant. The company has obtained intellectual property (IP) comprised of 10 patents covering its hardware. These capabilities allow Biobeat to support medical teams with tailored patient care such as adjustment of therapeutics and early prevention of specific disease exacerbation. Biobeat's wearable devices are the first devices to be FDA-Cleared for cuff-less non-invasive PPG-based blood pressure monitoring and are also CE Mark certified and cleared by Health Canada under the Emergency Use during the COVID-19 pandemic.

The Biobeat RPM platform is being used as a successful RPM tool by several HMOs in Israel, as well as by the Field Hospital team deployed to provide humanitarian aid during the Russian-Ukrainian conflict, allowing experts to look at the data remotely in real-time in Israel providing support to on-site medical teams.

The proposed project aims to apply the Biobeat platform in remote cardiac rehabilitation of high-risk congestive heart failure patients and to support the management and improve patient monitoring. Improvement is expected to be achieved by collecting a large set of cardiovascular and respiratory parameters that will allow medical staff to comprehensively review the patient's medical condition. By utilizing a user-friendly platform that allows remote rehabilitation and by analyzing the trend of each parameter, a tailored rehabilitation protocol will be developed to obtain optimal clinical outcomes.

The company has already started selling its products in the Canadian market and intends to further introduce its monitoring devices across Canada.

Ido Sadan, Coramaze Technologies Ltd.

Innovation: Tripair - Next Generation Percutaneous Treatment for Heart Failure Patients

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Coramaze Technologies is developing the Tripair, a percutaneous device for the repair of functional Tricuspid Regurgitation (fTR) in heart failure patients, to improve quality of life and reduce mortality. Our technology will enable treatment of tricuspid regurgitation patients, suffering from severe symptoms and poor prognosis.

The Tripair implant is anchored a-traumatically in the right atrium, allowing the heart team to assess efficacy using Echo imaging, before permanently implanting. A flexible joint enables the spacer balloon to "find its place" between the valve leaflets, sealing the regurgitant orifice area. Valve repair strategy is superior to replacement, when possible, due to normal leaflet function.

In the US, a prevalence of at least 1.6M isolated TR patients is estimated, with an incidence rate of 250K annually. Nevertheless, no transcatheter tricuspid repair device is approved for marketing, while investigational devices are proving complex to treat, with long procedure times and limited indications.

Kashif Khan, PLAKK Inc.

Innovation: Saving Lives One Scan at a Time: An Artificial Intelligence-Powered Ultrasound Analysis Tool to Characterize and Detect Unstable Plaques

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PLAKK Inc. is a Canadian-based digital health start-up that is pairing artificial intelligence (AI) with precision medicine to revolutionize the prediction and prevention of strokes, one of the leading causes of death and disability worldwide. Strokes are mainly caused by the rupture of unstable atherosclerotic plaques – fatty deposits that form in the arteries of the neck (carotid arteries) – that block blood flow to the brain. Currently, there does not exist any accurate clinical tool for 1) the early detection and diagnosis of unstable atherosclerotic plaques, and 2) prediction of stroke risk. This has led to 1 in 10 patients receiving an improper diagnosis and not getting the treatment they need, costing the Canadian health care system alone >$500 million each year, a number that is preventable with an earlier and more accurate diagnosis. This is of particular importance in remote and rural communities, where the burden of stroke is 20% higher in comparison to urban communities, which is partly due to the lack of specialized health services and available resources for preventative stroke care.

To address this clinical need, PLAKK's technology, SonoPlaqueTM, a cloud-based software, harnesses the power of AI and proprietary deep-learning algorithms to provide a more accurate, non-invasive, accessible, and faster approach to improve how healthcare professionals world-wide characterize and identify plaques in the carotid arteries that are at high risk of causing a stroke (i.e., unstable plaques). Specifically, it serves as a post-processing image analysis solution that 1) provides an analysis of ultrasound scans of the carotid arteries for automated detection and quantification of key plaque parameters (i.e., plaque thickness, artery stenosis, plaque morphology and composition), and 2) stratifies the individual according to stroke risk and the need for urgent care. This solution is targeted for any healthcare professional, regardless of their familiarity with ultrasound and plaque diagnosis, as the AI can guide them through each step of the analysis process; this is particularly useful in rural/remote areas where there is a lack of specialized care. To date, we have achieved an accuracy of 92% in

detecting and quantifying key parameters of the plaque (artery stenosis, plaque area, and plaque thickness), which are currently being validated externally by expert radiologists in the field of plaque diagnosis. At PLAKK, we are driven by the desire to improve the quality of life for patients suffering from atherosclerosis by preventing the occurrence of a devastating stroke and its debilitating consequences. Our goal is to enable healthcare professionals to intervene at the right moment so that patients get the appropriate treatment when they need it most.

We have established essential collaborations with leading Canadian academic and research centers to aid in the development of accurate algorithms for unstable plaque diagnosis: 1) Research Institute of the McGill University Health Centre [2020-present]: access to the largest biobank of its kind in North America (>650 patients and >13,000 images, blood biomarkers, and clinical information), and 2) York University [2021-present]: collaboration with research chair Dr. Ali Sadeghi who specializes in the quantification of ultrasound features using AI. Our current main focus is the recruitment of key opinion leaders in the field of radiology and cardiovascular medicine to test our product in clinical settings, as well as partner with leading ultrasound manufacturers to have our software available on their ultrasound platforms for a fast and immediate diagnosis.

Bradley Strauss, RBY Medical

Innovation: Angioplasty Support Sleeve for Peripheral Arterial Interventions

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Peripheral arterial disease (PAD) has been increasing with global estimates exceeding 230 million patients. Despite significant impact on patient mobility and quality of life, and high mortality rates with the most severe form of PAD known as critical limb ischemia, revascularization is infrequently performed in <1% of patients. However, the number and complexity of endovascular revascularization procedures is rapidly increasing. particularly in infra-popliteal procedures, which account for up to 70% of endovascular procedures in many sites. Endovascular procedures are now 4x more commonly performed than surgical revascularization.

Significant challenges still exist, particularly in infra-popliteal interventions due to the smaller size of the arteries and diffuse calcification. In selected cases, severely calcified superficial femoral artery lesions may also be technically challenging. The main problem is the ability to advance balloon catheters and stent catheters across lesions in these diffusely diseased, calcified and frequently tortuous arteries. Support and back-up for advancing balloon catheters is provided by sheaths, which are frequently inadequate due to the distance of the sheaths from the lesions, the passive form of support and the requirement to crossover the sheath from the opposite leg for access.

We have developed a novel catheter, known as a “support sleeve”, the first support device designed specifically for PAD interventions. The support sleeve, which is advanced through

conventional peripheral vascular sheaths, is designed to provide unparalleled support for peripheral microcatheters, angioplasty balloons and stents advanced over 0.014, 0.018 or 0.035" guidewires. The support sleeve provides an active form of support by virtue of a support balloon on the external surface of the support sleeve, which can be expanded from a range of 2-11 mm to strongly anchor the support sleeve against the arterial wall. The advancement of balloons and stents is further facilitated by a specific fixation wire (also known as a "wedge wire") mechanism that can couple and uncouple devices to the support sleeve.

The Angioplasty Support Sleeve addresses a significant need in PAD revascularization, where the market size is expected to aggressively expand from USD 7.9 billion in 2021 to 14.2 billion by 2028.

Shahar Figelman, Selfit Therapist Robot

Innovation: Selfit Therapist Robot

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Selfit is a digital robotic care startup focusing on aging population.

The company developed a unique human-machine operating system for people with common clinical disorders and for general age-related health maintenance.

It is a new way of interaction based on a therapist robot, which is used along the patient's journey from hospital care to home care and replaces human therapists when needed.

Selfit is working with the leading HMO's and hospitals in Israel as well as with the NHS in UK. The company's go to market product is focused on Stroke rehabilitation and engagement, all the way from acute to chronic stages.

Jonathan Maron, VenoVision

Innovation: VenoVision Hemodynamic Remote Monitoring Platform

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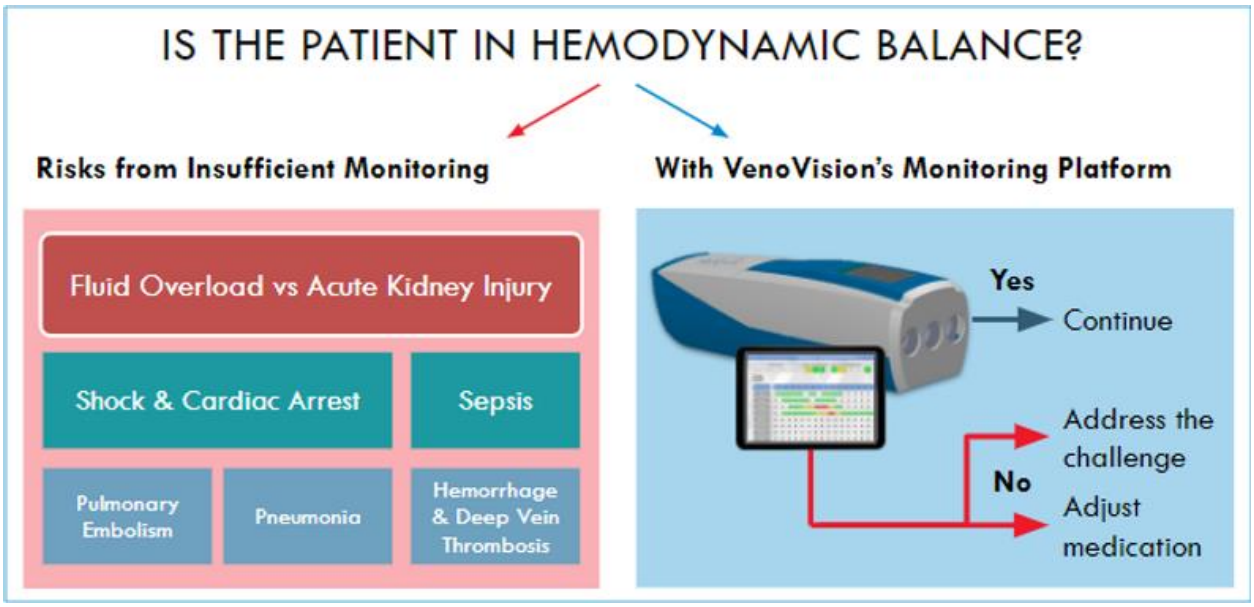
VenoVision aims to stabilize patients and reduce deterioration by setting a new frontier in low-cost, objective, non-invasive hemodynamic monitoring across the continuum of care. It will uniquely support medical teams to improve therapeutic management and outcomes of obese and overweight cardiovascular patients suffering, or at risk of, heart failure and hemodynamic complications.



Deep-thermal imaging device and monitoring platform:

- Easy to use, contactless, remote monitoring
- Overcomes the challenges of obese and overweight neck pathology
- All care settings - inpatient, outpatient, care facility, home or telemedicine

Multiparametric hemodynamic modalities:

- Signals processing algorithms to deliver data comparable to the Swan-Ganz or ultrasound
- JVP, CVP, venous waveform, RAP, HR, RR, PRQ and CO
- Additional right heart insights in the pipeline

Traction:

- TTO free, spin-off from the BioDesign Israel program of The Hebrew University
- Industry-funded (Terumo), proof-of-concept clinical trial completed at Shaare Zedek Medical Center on 15 patients (12 statistically significant). The technology showed a 20-fold stronger correlation to heart catheterization readings over the limited visual assessment
- Prototype designed and US Patent No. 11,234,643 (Feb'22)
- MassChallenge Israel 2021 finalist
- US researchers at Mayo Clinic (in discussion) eager to test VenoVision's potential

Biz model:

- Total addressable market >$15bn
- First 5 years, aim to reach 1.2m patients, with revenue of $60-135m
- Revenue model = Device + Patient Activation Fee + Monitoring/RPM Fee

Next steps:
VenoVision's next milestone will be to develop its current prototype into a fully working device with a user manual and an investigator brochure. This will also include achieving the FDA's BDD status, aligning the application towards CMS' NTAP qualification. Leveraging R&D, clinical trials and regulatory activities to this pathway, we aim to reach commercialization within 24 months.

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