MEDICALgorithmics
INNOVATIVE SOLUTIONS IN MEDICINE


# Biofund investment in Medicalgorithmics

## Functional merger of MDG with Kardiolytics

Kardiolytics

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17 October 2022

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# Presenting today

## Maciej Gamrot

MDG CFO

Previously at:
PWC, EY, Agora, Platige Image, Audioteka, Dobroplast Fabryka Okien/ Arbonia A.G.

Education:
University of Łódź; ACCA, CIA

CFO of Medicalgorithmics since 2021.

## Jarosław Jerzakowski

MDG Board Member

Previously at:
Konica Minolta Business Solutions, Adrem Software

Education:
Cracow University of Economics; University of Mannheim,

At Medicalgorithmics since 2013 responsible for foreign business development outside the USA

## Dr. Kris Siemionow, MD PhD

Kardiolytics/Biofund

Previously at:
University of Illinois, Holosurgical, Inteneural Networks

Education:

Cleveland Clinic Lerner College of Medicine, Ohio University, PUM

Founder of Holosurgical and Inteneural; AI-based medtech companies, both acquired; co-founder Dystrogen Therapeutics, co-foudner Biometryks; co-founder of Biofund

## Przemysław Tadla

Kardiolytics, COO

Previously at:
Medicalgorithmics, UL Intenational

Education:

Poznan University of Technology, Master's degree, Automatic Control Engineering and Management

Last 15 years in the Med-Tech industry; Medicalgorithmics, Biometryks & Kardiolytics and in the certification industry at UL International. 2013 to 2021 at Medicalgorithmics as Strategy Director, and later as an Operations and Product Compliance Director.

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# MDG current, pre-merger outlook

1) **Stabilized liquidity and financial situation, “clean” auditor’s report after the review of the semi-annual financial statements**
2) **Significant revenue concentration and dependence on a major customer and US market**
3) **Need for additional investments to accelerate the completion of key technology projects**

# Merger rationale

- Kardiolytics break-through technology
- 170,000+ patients undergo long-term ECG monitoring using MDG technology, globally
- 2,000+ US cardiologists are currently active users of MDG products and will have access to Kardiolytics products
- Kardiolytics will leverage the current MDG patient base to accelerate penetration of the market by VCAST

Kardiolytics

**Unique AI technology for heart structure imaging**

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**Unique AI for ECG analysis**

# Key transaction benefits and goals

1) Increase revenue
2) Optimize the cost structure
3) Complete the key technologies and obtain the related regulatory clearances
4) Start executing on a new, clear technology roadmap
5) Regain investor credibility

# Key transaction highlights

- **Offer valued at PLN 220m for the acquisition of 49.99% of new shares and votes**
  A cash contribution of PLN 13.8m and an in-kind contribution of all shares in Kardiolytics, which are valued at USD 44.9m (appraisal of Baker Tilly TPA). A cash contribution of PLN 13.8m within 36 months as (if) needed

- **Value creation potential from synergistic merger of offerings from MDG and Kardiolytics**
  Leveraging MDG client and patient base, doubling competence of AI technology in cardiological diagnostics and monitoring, sharing other know-how and resources: FDA approvals, distribution networks, US contact and presence, corporate resources.
  The sole competition in the Kardiolytics space is HeartFlow with a valuation of more than $2 billion [1]

- **New leadership and direction**
  Biofund comes with clear strategic vision, scientific background and strong business track record

- **Attractive valuation – 44.27 PLN per share**
  Approximately 6x higher than the market value prior to the deal announcement; after the announcement stock price almost doubled

- **Conclusion of the strategic options review**
  By signing the investment agreement with Biofund, MDG Management Board has concluded its strategic options review

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1. https://cdn-corpweb.heartflow.com/assets/docs/HeartFlow_-_Investor_Presentation_2021-10.pdf, https://app.dealroom.co/companies/heartflow/

# Transaction structure

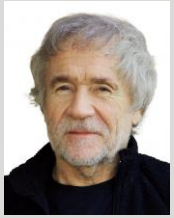
- **Biofund Capital Management LLC to acquire 49.99% - 4,976,384 new shares** for PLN 13.8m in cash and 100% shares in Kardiolytics valued by Baker Tilly TPA at USD 44.9m
- **The issue price PLN 44.27 per share**
  Nearly 6x times the average pre-deal share price of PLN 7.66
- **Corporate Governance**
  For two years following the Transaction Closing, Investor will vote for the election of two members of the Supervisory Board from among candidates proposed by the Company's minority shareholders, other than individual shareholders, who hold shares that entitle them to no less than 3% and no more than 10% of votes

# About Kardiolytics and Biofund

The mission of Biofund is to develop and facilitate the use of advanced technologies based on AI to dramatically accelerate progress in medicine, make advanced medical procedures available to those who currently have no access to advanced care and this way, make the world a better place.

Kardiolytics Inc. is one of Biofund members. It is a Chicago-based Artificial Intelligence company specializing in Cardiology. The company was founded in 2018 by a pioneer in Data Mining and Big Data Learning - Paul Lewicki PhD (the founder of StatSoft and STATISTICA) and a surgeon Kris Siemionow MD, PhD (the founder of Holosurgical and Inteneural; AI-based medtech companies, both acquired), and it includes a team of clinicians, researchers, and AI software engineers. The headquarters and R&D center are located in the US (Chicago), with the external support of two other R&D groups located in Poland (Poznan and Zabrze).

The goal of Kardiolytics is to make advanced, highly accurate diagnostics of the heart - inexpensive and widely available, including the parts of the world that currently have limited access to advanced medical diagnostics. The technology developed by Kardiolytics allows clinicians to rapidly analyze medical imaging data of the heart and its blood vessels in order to allow doctors to effectively develop treatment plans.



**Prof. Paul Lewicki, PhD**

THE UNIVERSITY of TULSA

- Past Professor of Psychology UT
- Founder and CEO of StatSoft (acquired by Dell in 2014)
- Big Data Pioneer
- Entrepreneur, large multinational company CEO (StatSoft had 30 overseas offices in all major markets and over 1M B2B users across various industries)
- Past director NASDAQ med tech company
- h-index 22
- >8,000 citations

**Dr. Kris Siemionow, MD, PhD**

Cleveland Clinic

- Past Chief of Spine Surgery and Associate Tenured Professor of Orthopaedics and Neurosurgery at the University of Illinois
- Past Co-founder Holosurgical (AI for neurosurgery)
- Past Co-founder Inteneural Networks (Brain MRI analytics); acquired
- Past Chief Medical Officer NASDAQ medtech
- Over 100 scientific publications
- Over 50 patents
- h-index 18

Kardiolytics DYSTROGEN THERAPEUTICS Surgalign HOLOSURGICAL

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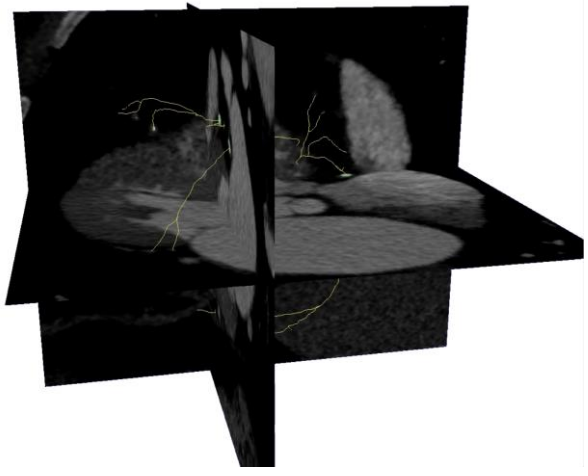
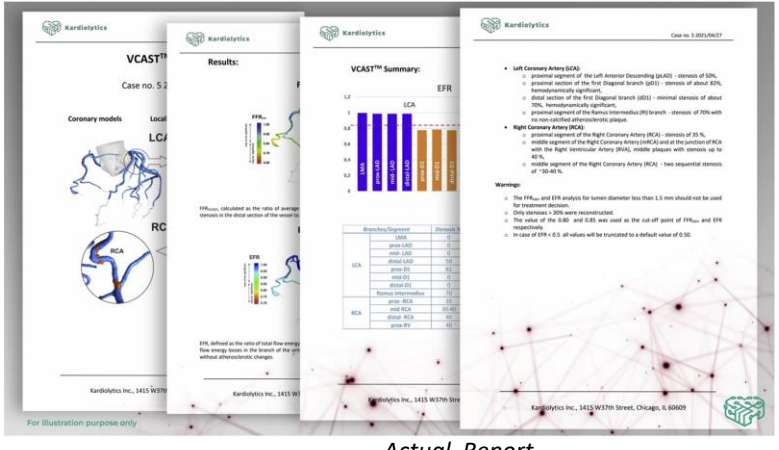
# Kardiolytics: technology overview

Kardiolytics Inc. has developed technology that uses Artificial Intelligence to derive crucial diagnostic information about narrowing of the heart blood vessels (atherosclerosis), from inexpensive and widely available imaging (CT-scans) of the heart. This diagnostic information has been one of the most important and most widely used in Cardiology, but one that normally can be obtained only by applying complex, expensive, and highly invasive procedures that involve inserting probes into the heart and require highly qualified staff and infrastructure.






*Actual Report*

The Kardiolytics cardiac test (VCAST) is rapid, inexpensive and entirely noninvasive. It provides personalized, color-coded, 3D modeling of the coronary arteries combined with detailed, functional diagnostic information regarding blood flow. This includes computed quantities of blood, pressure, and velocity and is designed to assist the physician both in completing the diagnosis and designing the treatment plan for coronary artery disease.

VCAST is a cloud-based software, and its unique technological advantage is a set of AI algorithms for segmentation and stenotic vessel reconstruction.

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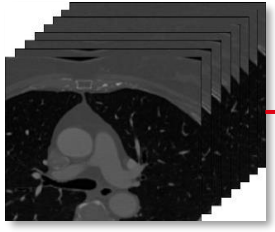
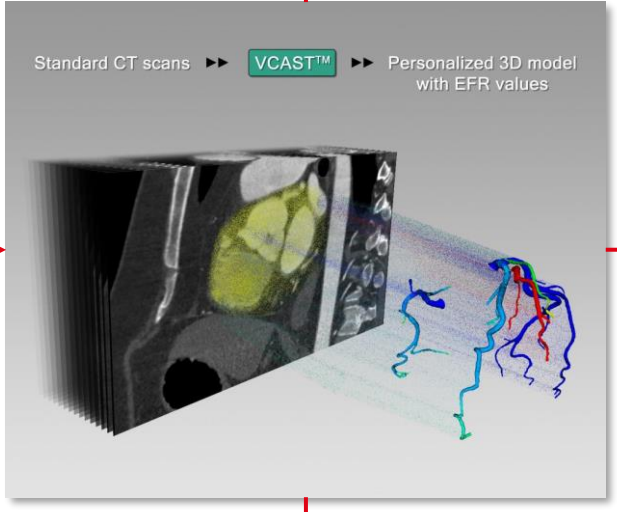
# Kardiolytics: VCAST supported patient diagnostics

Raw DICOM



Standard CT scans ▸▸ VCAST™ ▸▸ Personalized 3D model with EFR values

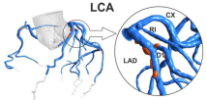


Regular screening

No CAD

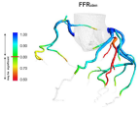
Pharmacotherapy

Early stage of CAD, minor plaque deposits




Invasive therapy

Advanced CAD with artery blockage



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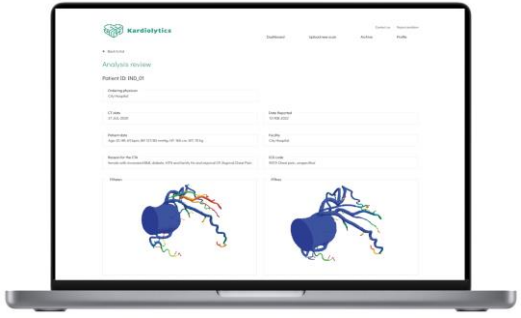
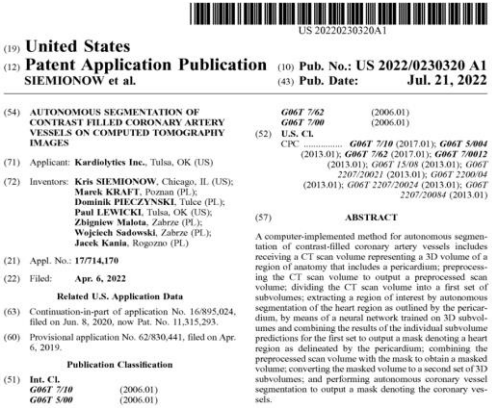
# Kardiolytics: intellectual property

Kardiolytics Inc. holds a wide range of patents and patent applications pending (10) protecting the technology used by VCAST system. Among the most important ones are:

- Autonomous segmentation of contrast filled coronary artery vessels on computed tomography images
- Method for determining the significance of stenosis
- Method for machine learning based segmentation of contrast filled coronary artery vessels on medical images
- Method for modeling blood vessels and blood flow




US2021290076A1; EP3884848A1; EP3719744A1; US2020105420A1; EP3629341A1; US2020320751A1; EP3726460A1; US2020349712A1



US 20220230320A1

(19) **United States**

(12) **Patent Application Publication**
**SIEMIONOW et al.**

(10) **Pub. No.: US 2022/0230320 A1**

(43) **Pub. Date: Jul. 21, 2022**

(54) **AUTONOMOUS SEGMENTATION OF CONTRAST FILLED CORONARY ARTERY VESSELS ON COMPUTED TOMOGRAPHY IMAGES**

(71) Applicant: **Kardiolytics Inc.**, Tulsa, OK (US)

(72) Inventors: **Kris SIEMIONOW**, Chicago, IL (US); **Marek KRAFT**, Poznan (PL); **Dominik PIECZYNSKI**, Tulce (PL); **Paul LEWICKI**, Tulsa, OK (US); **Zbigniew Malota**, Zabrze (Pl.); **Wojciech Sadowski**, Zabrze (PL); **Jacek Kania**, Rogozno (PL.)

(21) Appl. No.: **17/714,170**

(22) Filed: **Apr. 6, 2022**

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 16/895,024, filed on Jun. 8, 2020, now Pat. No. 11,315,293.

(60) Provisional application No. 62/830,441, filed on Apr. 6, 2019.

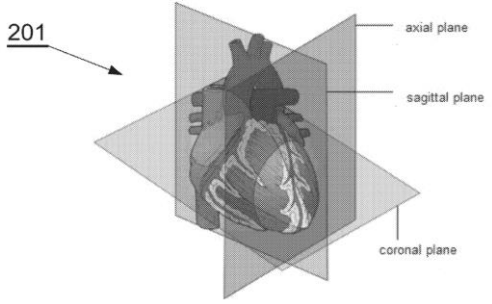
**Publication Classification**

(51) **Int. Cl.**
***G06T 7/10*** (2006.01)
***G06T 5/00*** (2006.01)
***G06T 7/62*** (2006.01)
***G06T 7/00*** (2006.01)

(52) **U.S. Cl.**
CPC ..... ***G06T 7/10*** (2017.01); ***G06T 5/004*** (2013.01); ***G06T 7/62*** (2017.01); ***G06T 7/0012*** (2013.01); *G06T 15/08* (2013.01); *G06T 2207/20021* (2013.01); *G06T 2200/04* (2013.01); *G06T 2207/20024* (2013.01); *G06T 2207/20084* (2013.01)

(57) **ABSTRACT**

A computer-implemented method for autonomous segmentation of contrast-filled coronary artery vessels includes receiving a CT scan volume representing a 3D volume of a region of anatomy that includes a pericardium; preprocessing the CT scan volume to output a preprocessed scan volume; dividing the CT scan volume into a first set of subvolumes; extracting a region of interest by autonomous segmentation of the heart region as outlined by the pericardium, by means of a neural network trained on 3D subvolumes and combining the results of the individual subvolume predictions for the first set to output a mask denoting a heart region as delineated by the pericardium; combining the preprocessed scan volume with the mask to obtain a masked volume; converting the masked volume to a second set of 3D subvolumes; and performing autonomous coronary vessel segmentation to output a mask denoting the coronary vessels.

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# Kardiolytics: VCAST product development roadmap

Ongoing development and preparation for clinical study [Q4 2023 / Q1 2024]

Development planning [Q1 2025]

Research phase [Q1 2026]

**VCAST v 1.0**

Analysis workflow powered by AI-algorithms:

- CT-scan data uploaded to the cloud
- Segmentation of 3D models – vessel mesh models
- Vessel reconstruction using the mesh models
- Numerical simulation performed in AWS cloud
- Stenosis detection and vessel analytics available through the web application
- Automatically generated reports containing comprehensive, color-coded 3D images and diagnostics

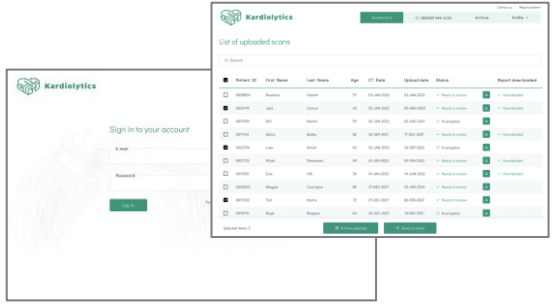
**VCAST v 2.0**

Significant progress towards the ultimate goal of creating a completely autonomous, automatic cardiovascular diagnostics system, where reports will eventually be generated with no necessity for human supervision at any stage of the analysis.

Some limited level of human supervision will still be necessary in v 2.0

**VCAST v 3.0**

Product enhancements based on Big Data Learning, and guided by specific feedback and requests of cardiologists - users of VCAST v 1.0 and 2.0

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# Kardiolytics: competitive landscape

| | Kardiolytics VCAST™ | HeartFlow® | cleerly |
|---|---|---|---|
| **FFRct** | ✔ | ✔ | – |
| **RFR** | ✔ | – | – |
| **EFR** | ✔ | – | – |
| **Stenosis** | ✔ | ✔ | ✔ |
| **Plaque assessment** | Full | Full | ● Non-Calcified Plaque (NCP)<br>● Calcified Plaque (CP)<br>● Low-Density Non- Calcified Plaque (LD- NCP) |
| **Distance Measurements** | ✔ | ✔ | ✔ |
| **Segmentation of region of interest** | Automatic | Manual and Semi-Automatic | Manual and Semi-Automatic |
| **Turnaround time** | < 2h | > 4h | > 2h |
| **Product Approvals** | USA, Europe (planned) | USA, Europe, Japan | USA |
| **Amount Raised** | - | $650M | $280M |
| **Company Valuation** | N/A | $2.4b [1] | $0.9—1.3b [2] |

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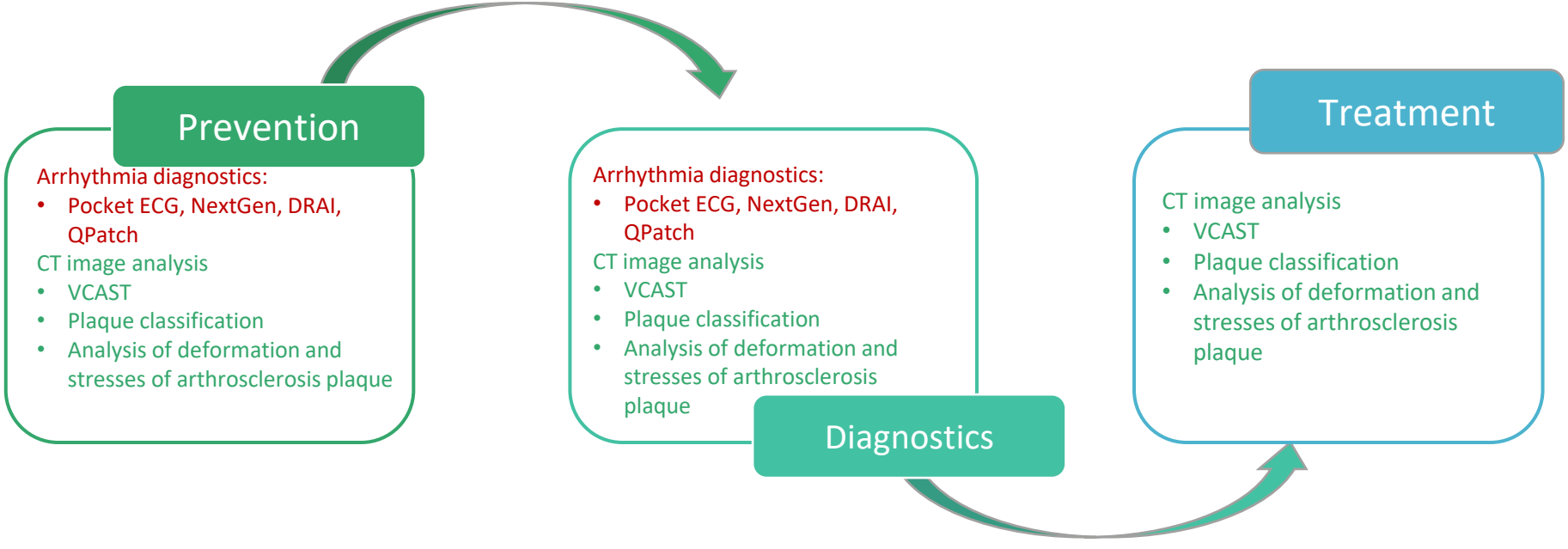
1. https://cdn-corpweb.heartflow.com/assets/docs/HeartFlow_-_Investor_Presentation_2021-10.pdf, https://app.dealroom.co/companies/heartflow/ 2. https://app.dealroom.co/companies/cleerly_1

# 2023 POST MERGER KL-MDG product portfolio

**The combined MDG+KL portfolio of products by the end of 2023 can diagnose and treat a population of 10 million+ potential patients in the USA alone**



# NEW product portfolio – business continuity products (SHORT TERM)

**NextGen software**

- Web-based platform for ECG analysis. The successor of the PC Client software
- NextGen is integrated with DRAI and can analyse signals recorded by Qpatch and PocketECG
- Can deliver automatically generated reports
- Can be integrated with third-party ECG devices

NextGen(cloud) software platform

**P4 LTEm**

- An updated and upgraded version of the “tried and true” PocketECG recorder developed for the OUS markets
- Integrated with the NextGen software
- Has a communication module compatible with telecommunication infrastructure worldwide


**DRAI**

- AI algorithm that can automatically analyze signals from Q Patch and PocketECG IV

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# Under development and review (MID TERM)

**VCAST**

Automatic analysis workflow powered by AI algorithms:

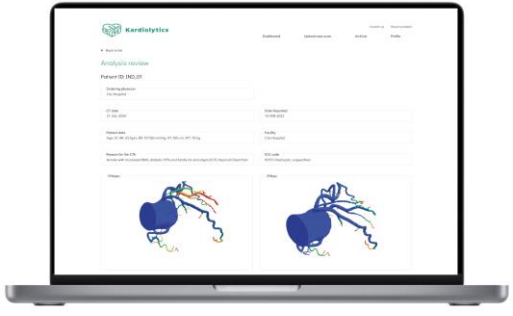
- AI-powered coronary analysis for uploaded CT-scans (Segmentation of 3D models and vessel reconstruction using the mesh models)
- Numerical simulation performed in AWS cloud
- Plaque location and basic plaque classification - soft, calcified
- User will have available vessel parameters like color-coded diameter and diameter in mm, degree of coronary stenosis and FFR value
- Automatically generated reports

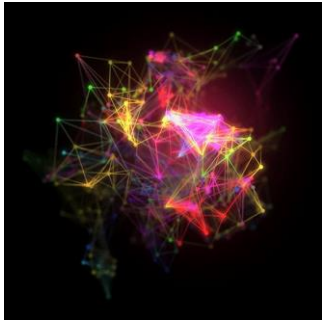
**NextGen P5 Monitor**

- The product will allow monitoring patients with arrhythmia, CHF, undergoing cardiac rehab
- 2 in 1 device. Modular, multichannel ECG device (Patch, 4 channel Holter & MCT)
- Built-in additional sensors: temperature, SpO2, microphone
- Compatible with MDG AI algorithms

**DRAI 2.0**

- AI algorithm that can automatically analyze signals from Patch (including third-party products), multichannel Holter, and MCT ECG recordings (including third-party products)





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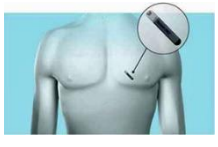
# NEW product portfolio and new research projects (LONG TERM)

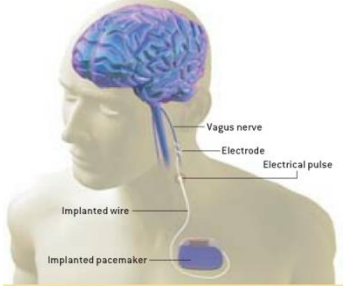
**NextGen ICM**

- Implantable Cardiac Monitoring is a device for very long-term cardiac patient AI-driven monitoring (up to 3 years)
- The product is designed to detect arrhythmias and all basic vital parameters in patients with Congestive Heart Failure
  - Cough, heart and lung auscultation
  - Position and activity
  - Temperature



**Vagal Nerve Stimulator (VNS)**

- Implantable device for treatment of Heart Failure patients
- It is designed to treat patients recovering from heart attack and stroke
- It is also designed to be used for rheumatoid arthritis, epilepsy and depression treatment




**Long-term wellbeing monitoring**

- Cooperation with wearable device manufacturers
- The goal is to build a new type of AI-based software for long-term monitoring of patients with a wide variety of disorders
- The new software will use PPG data together with additional information collected by the patient's phone and smartwatch (i.e., in the Apple Health app) to support healthy living

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# Strategic Initiatives roadmap

## NOW

- New Corporate Strategy for the next 3 years
- New technology roadmap aligned with Corporate Strategy (Imaging & ECG products)
- Employment optimization, Gap analysis of required staff needed to deliver new technology roadmap
- RnD reorganization and expansion based on the identified gaps in competencies
- Overhaul of marketing, KOLs, rebuilding Investor Relations
- KPIs for each team – to be reviewed monthly, quarterly and annually
- Initiation of the validation testing of VCAST 1.0
- Initiation of R&D of NextGen P5 for arrhythmia with CHF monitoring capabilities (multisensor, modular device)

## SHORT TERM

- MDG NextGen launch in the USA
- MDG NextGen launch OUS
- QPatch launch for the US customers
- Acquire 5 customers for DRAI licensing - test of the new business model
- Strategic partnership with at least 3 big ECG equipment manufacturers
- VCAST 1.0 FDA certification
- Initiate VCAST 1.0 CE Mark (Q1)
- Continue with VCAST 2.0 R&D
- New research projects – Start NextGen ICM for cardiac patient monitoring (arrhythmia, CHF)
- Non-dilutive financing (NCBiR, etc.) for R&D projects

## MID TERM

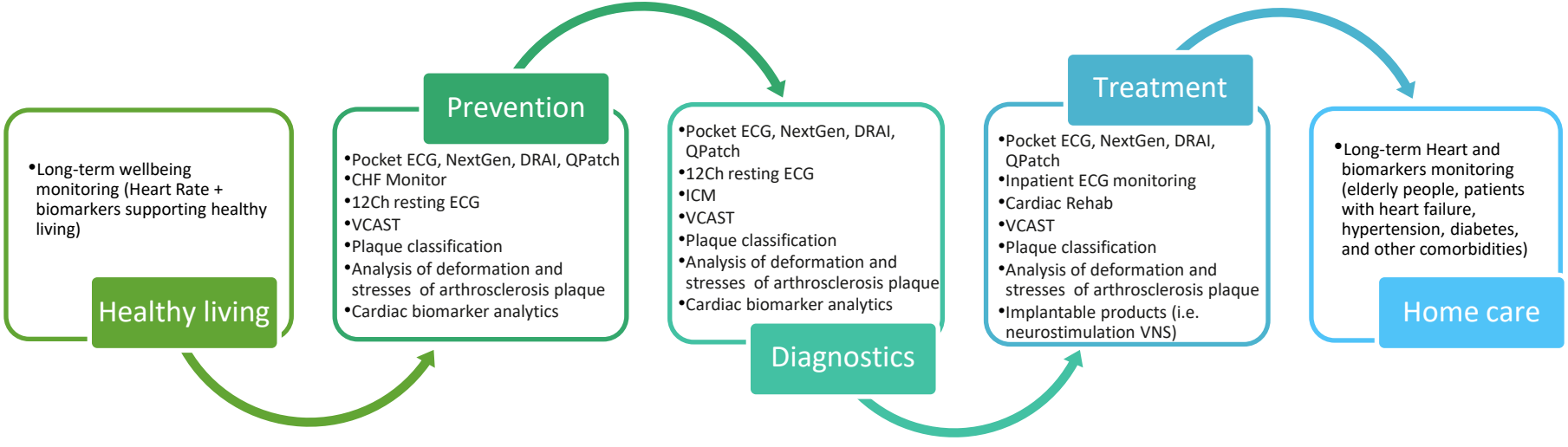
- VCAST commercial launch for the US customers
- VCAST 2.0 FDA certification
- Initiate VCAST 3.0 RnD
- Launch NextGen P5 v1.0 for arrhythmia with CHF monitoring capabilities (multisensor, modular device: patch and PocketECG capabilities)
- Initiate Vagal Nerve Stimulator (VNS) for Heart Failure RnD
- NextGen ICM first in Man
- NextGen ICM start certification

## LONG TERM

- Initiation of the VCAST sales in the EU + Australia + Canada
- Launch NextGen ICM for cardiac patient monitoring (arrhythmia, CHF)
- VNS first in man
- Initiate VCAST 4.0 RnD

# 2025 Future product portfolio for the WHOLE cardiology department

**Fully leveraging the know-how of combined MDG+KL will by 2025 create a comprehensive portfolio of technologies covering all stages of the cardiac patient journey**



# Summary

1) AI powered medical technology company

2) Increased revenue and profitability

3) Optimized operations

**Regain investor credibility and increase shareholder value**

# Next steps

1) **October 28 2022 Transaction to be voted on by shareholders**

2) **Biofund and MDG to decide on the fulfilment of the Investment Agreement conditions and on the execution of the transaction**


# Q&As


# Appendixes

# Currently planned use of funds

**70%** MEDICALgorithmics

- Diversify US distribution (New US distribution for VCAST and strengthen MDG distribution worldwide)
- Speed up NextGen release
- QPatch introduction to the US and EU market
- DRAI as an independent product for third party medical products
- Initiation of AI research in the area of resting ECG, signals collected by wearables, automation of the analysis workflow
- Hiring - marketing, business development, sales

**30%** Kardiolytics

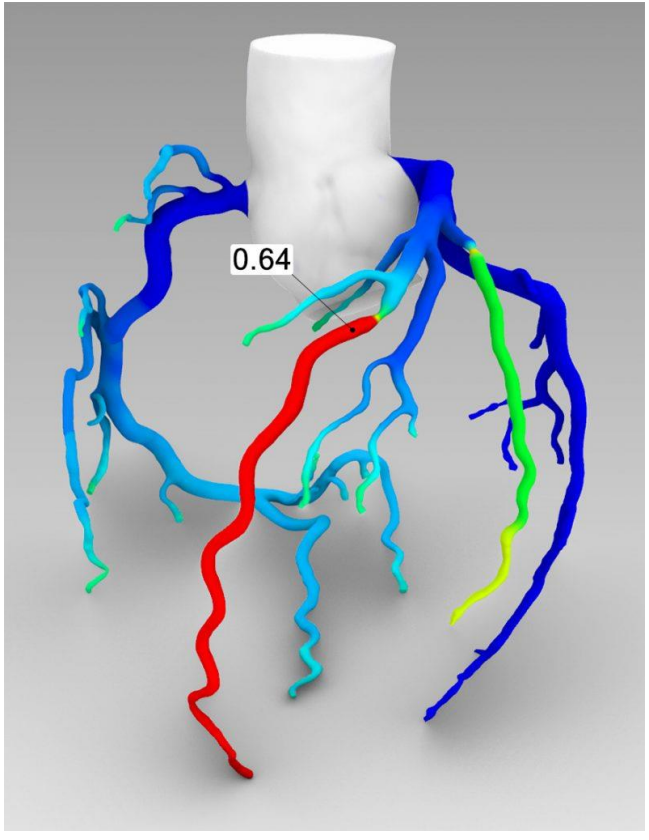
- FDA certification (510k)
- New AI algorithms for plaque analysis and calcium score assessment
- Clinical research in the areas of flow analysis, plaque, calcium score
- VCAST integration with PACS systems

**Commitment by BioFund to provide additional financing up to PLN 13,8m to combined entity for min. 36 months (as needed):**

- To speed up combined entities growth
- Especially if Medi-Lynx contract is terminated
- To support strategic acquisitions and co-development agreements
- To support NCBIR and other grant financing (grants for the research projects aiming to automate the analysis process of ECG and imaging data)

# Kardiolytics reimbursement

- ✓ Centers for Medicare & Medicaid Services have established numerous reimbursement codes where VCAST can be used.
- ✓ The VCAST meets the requirements of $FFR_{CT}$ and plaque analysis reimbursement codes
- ✓ Centers for Medicare & Medicaid Services (CMS) have established a national payment rate for the $FFR_{CT}$ Analysis in office-based settings, such as doctors' offices and imaging centers of $930.34
- ✓ For the analysis in the hospital outpatient setting CMS continues to provide a national payment rate of $950.50
- ✓ New reimbursement code for automated quantification and characterization of coronary atherosclerotic plaque to assess the severity of coronary disease, using data from coronary computed tomographic angiography. The estimated rate is ~$1,000



# Benefits from the transaction - global leader

- The merger is a strong fit for both companies' strategy to transform cardiac patients monitoring and treatment: the combination of Kardiolytics' breakthrough imaging technology for the inpatient setting with Medicalgorithmics' leading cardiac diagnostics and monitoring technology for the outpatient setting
- The total Addressable Market for the combined portfolio will be 10 million+ patients in the USA
- Kardiolytics state-of-the-art AI for heart imaging combined with Medicalgorithmics AI for the ECG analysis enables building a future global leader in patient care management solutions cardiac patients from the hospital and outpatient populations
- Product Portfolio innovation - With our collective portfolios, AI expertise, and services platforms, we will be in an optimal position to improve patient care across care settings for cardiac diseases and medical conditions
- Operational efficiencies due to shared sales and marketing teams

Kardiolytics

**Unique AI technology for heart structure imaging**

MEDICALgorithmics

**Unique AI for ECG analysis**

MEDICALgorithmics
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