



Treatment Decisions With Greater Confidence

2022-06-20--21

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# About us

## **Anders Rylander, CEO & Board Member**

- Main shareholder in Biovica
- Co-founder of Axholmen AB
- CTO at ICA AB
- Senior Manager at Accenture



## **Cecilia Driving, EVP CFO**

- Board member & chair audit committee Ovzon AB
- CEO RISE Research Institutes of Sweden AB
- CFO MedCap AB
- CFO Diamyd Medical
- CFO & Legal Mando AB



# Agenda

- 1. Company & Product Overview**
2. Clinical Evidence & Collaborations
3. Market
4. Team
5. Summary

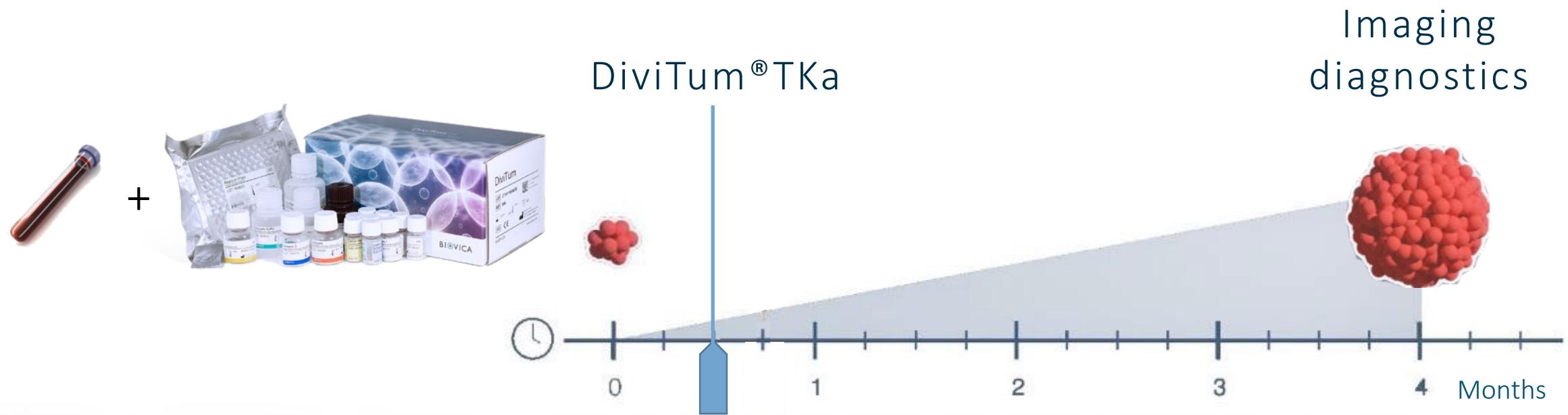


# Biovica Overview

- Founded 2009, based on research performed at Uppsala University
- IPO 2017, traded on Nasdaq First North Premier
- HQ in Uppsala, lab in San Diego
- Regulatory: ISO 13485 certified and DiviTum® TKa CE labeled
- FDA 510(k) submission Q3 2020



# DiviTum®TKa Provides Early Response Indicator of the Effectiveness of Treatment For Cancer Patients



DiviTum®TKa measures cell proliferation rate for faster evaluation of cancer treatment efficacy.

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# Strong Clinical Results and Data for DiviTum®TKa Peer-Reviewed & Published in Clinical Oncology Journals

- 24 published and peer-reviewed articles with DiviTum®TKa
- Summary of results from articles:
  - Prognostic: risk for cancer recurrence, progression & survival
  - Monitoring: quick feedback on treatment efficacy

Cancer area	Patients	No of Studies
 Breast Cancer	1,293	13
 Gastrointestinal	713	4
 Lung Cancer	281	2
 Blood Cancer	440	4
 Other	368	1
	3,095	24



Summary of clinical results available at [biovica.com](http://biovica.com).

# Collaborations with Key Opinion Leaders

- selected from ongoing or completed clinical trials



**Matthew P. Goetz**  
M.D, Professor  
Mayo Clinic



**Daniel F. Hayes**  
M.D, Professor  
University of Michigan  
Ex. ASCO President  
SWOG Transl. Med.



**Cynthia X. Ma**  
M.D, Professor  
Washington University



**Geoffrey Shapiro**  
M.D, Ph.D, Professor  
Dana-Farber Cancer  
Institute



**Matthew J. Ellis**  
M.D, Professor  
Baylor Collage



**Gabriel N. Hortobagyi**  
MD, FACP, Professor  
MD Anderson Cancer Center  
Ex ASCO President



**Luca Malorni**  
M.D, Ass. Professor  
Hospital of Prato  
Baylor Collage



**Martine J. Piccart**  
M.D, Professor  
Université Libre de Bruxelles  
Founder Big against BC  
Ex. ESMO President



**Jonas Bergh**  
M.D, Professor  
Karolinska Institutet  
ESMO BC Award  
Ex Chairman SweBCG  
EMA Advisory Group  
Member Nobel Assembly



**Sacha Howell**  
M.D, PhD  
Senior Lecturer and Honorary  
Consultant in Medical Oncology  
The Christie NHS Foundation Trust



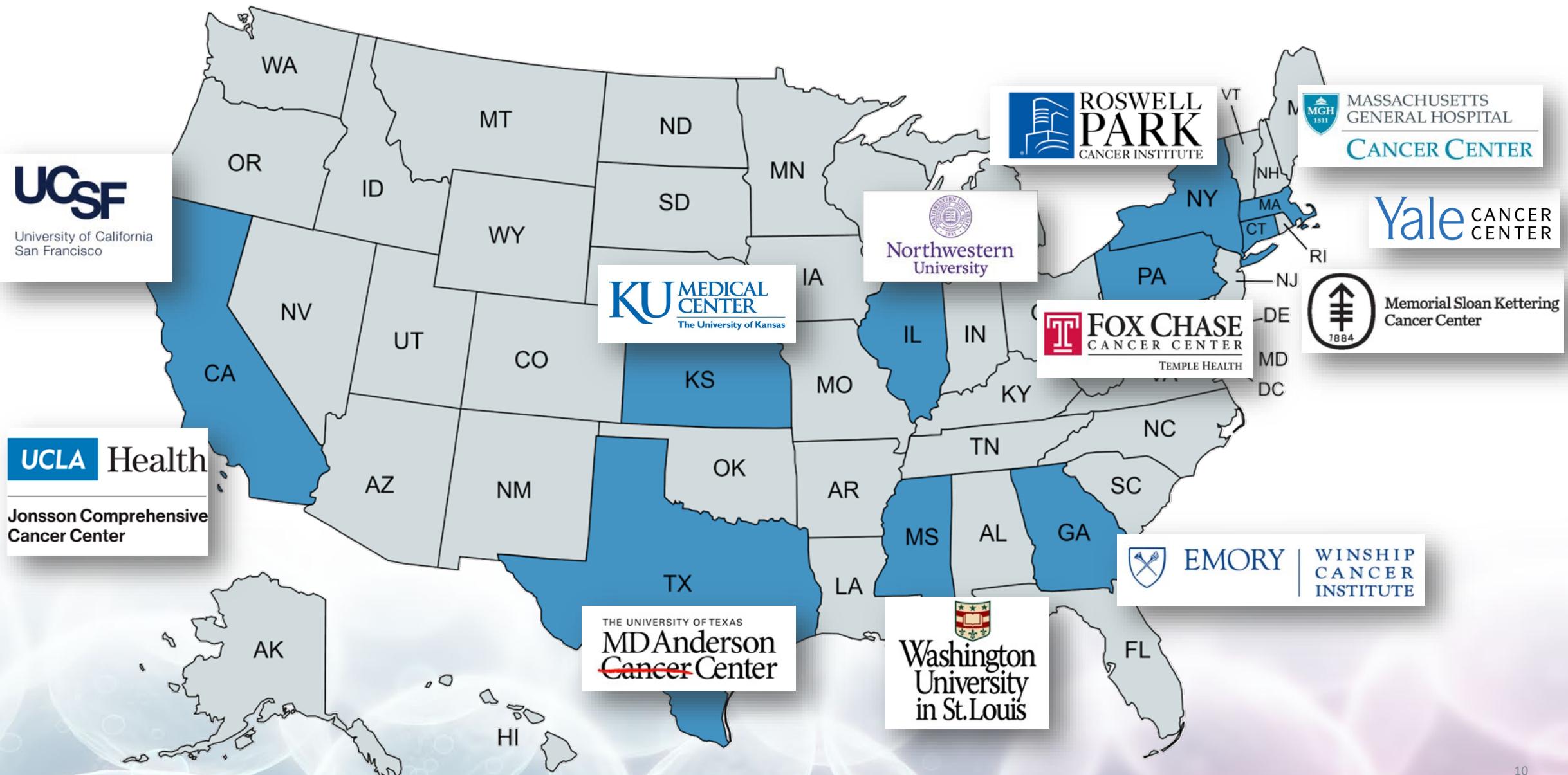
**Thomas Hatschek**  
M.D, PhD  
Karolinska Institutet



**Amelia McCartney**  
BSc BA (Hons) MBBS FRACP  
Hospital of Prato  
Monash Health, Melbourne

Support from leading KOL's is a critical success factor for clinical acceptance!

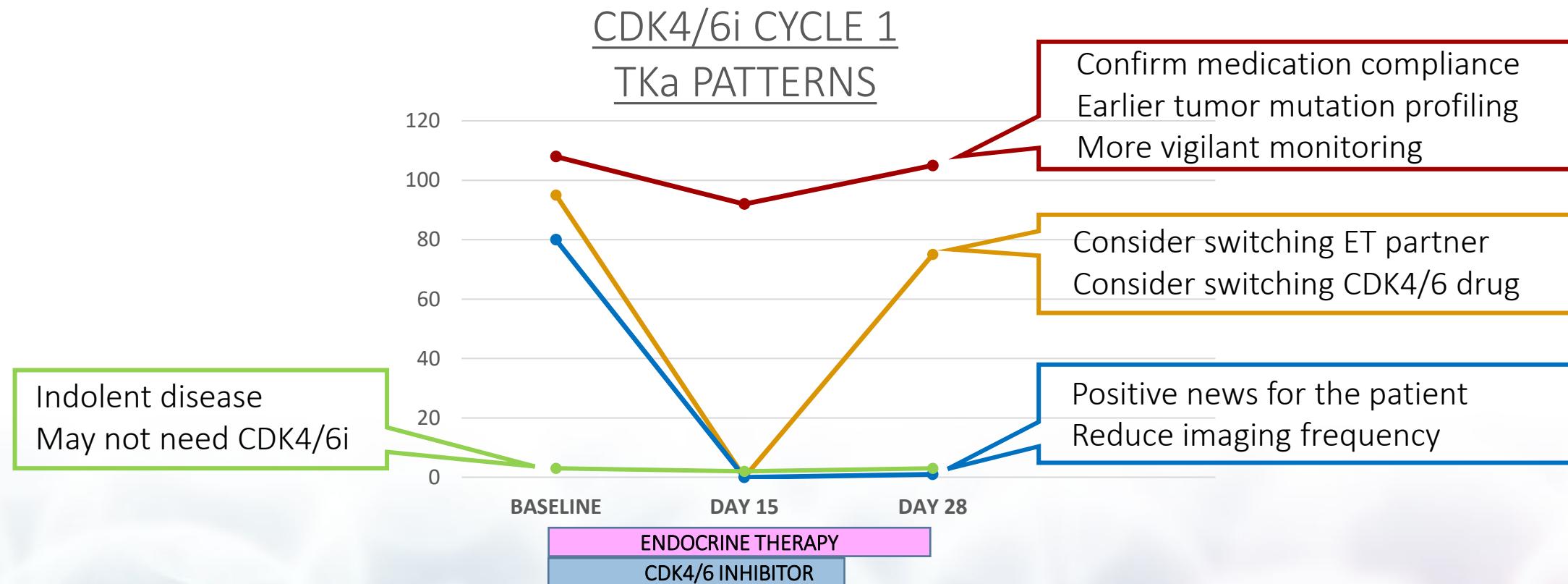
# Scientific Advisory Boards (USA) during 2021



# Utility of DiviTum-TKa in Clinical Practice

Prediction of CDK4/6i response based on cycle 1 TKa pattern

BIO+VICA



Based on data from BioltaLEE & PYTHIA trials

# DiviTum®TKa results from PYTHIA published in EJC

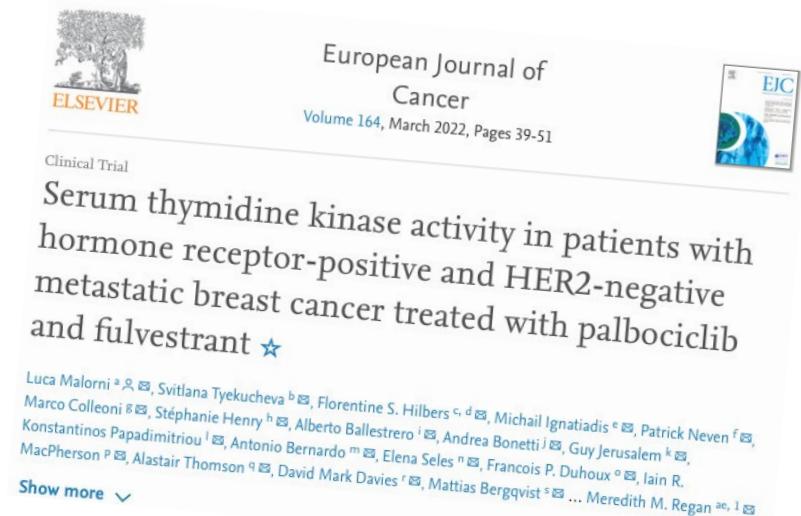
## Summary:

- 122 patients, metastatic breast cancer, CDK4/6i treatment
- Patients that had low DiviTum®TKa-result two weeks into treatment, had significantly better progression free survival after six months (85% vs 17%)
- DiviTum® may be used as a novel biomarker to select patients for alternative treatment modalities.

*"The results support that serum TK activity can be a biomarker to identify those patients who will have an adverse outcome to the treatment with fulvestrant in combination with palbociclib, which represents the most current and active treatment standard for patients with metastatic, endocrine resistant estrogen receptor positive and HER2 negative breast cancer.*

*TK activity measured after only two weeks of therapy gives us a strong indication on the clinical outcome independently from other clinical parameters. Even though further investigation in prospective comparative trials is warranted, these results are highly encouraging and highlight the potential of DiviTum®TKa to evaluate treatment efficacy already during the first weeks of therapy, and afterwards to monitor the disease."*

Luca Malorni, Principal Investigator of the study at Prato Hospital, Italy



# Positive DiviTum®TKa results published in npj Breast Cancer (a Nature publication)

## Summary:

- 51 patients, metastatic breast cancer, CDK4/6i treatment
- Responders had significantly lower baseline Tka
- DiviTum®TKa predicted disease progression 83 days in median ahead of imaging

*“The results from our study support using DiviTum®TKa to monitor efficacy during treatment and predict response to palbociclib, a standard therapy for women with metastatic breast cancer. It is interesting to learn that DiviTum®TKa can identify progression many months ahead of imaging”*

Jairam Krishnamurthy, Principal Investigator of the study at Division of Oncology/Hematology, University of Nebraska Medical Center.

**npj Breast Cancer**

**ARTICLE** **OPEN** [www.nature.com/npjbreastcancer/](https://www.nature.com/npjbreastcancer/) [Check for updates](#)

A phase II trial of an alternative schedule of palbociclib and embedded serum TK1 analysis

Jairam Krishnamurthy  <sup>1,2</sup>, Jingqin Luo  <sup>2</sup>, Rama Suresh <sup>3</sup>, Foluso Ademuyiwa  <sup>3</sup>, Caron Rigden <sup>3</sup>, Timothy Rearden <sup>3</sup>, Katherine Clifton <sup>2</sup>, Katherine Weilbaecher <sup>2</sup>, Ashley Frith <sup>2</sup>, Anna Rosenthal <sup>2</sup>, Pavon K. Tandra  <sup>2</sup>, Mathew Cherian <sup>1,3</sup>, Tracy Summa <sup>3</sup>, Brittnie Haas <sup>2</sup>, Shana Thomas <sup>3</sup>, Leonel Hernandez-Aya <sup>3</sup>, Mattias Bergqvist  <sup>2</sup>, Lindsey Peterson <sup>2</sup> and Cynthia X. Ma  <sup>1,2</sup>

Palbociclib, 3-weeks-on/1-week-off, combined with hormonal therapy, is approved for hormone receptor positive (HR+)/HER2-negative (HER2-) advanced/metastatic breast cancer (MBC). Neutropenia is the most frequent adverse event (AE). We aim to determine whether an alternative 5-days-on/2-days-off weekly schedule reduces grade 3 and above neutropenia (G3+ANC incidence). In this single-arm phase II trial, patients with HR+/HER2- MBC received palbociclib 125 mg, 5-days-on/2-days-off, plus letrozole or fulvestrant per physician, on a 28-day cycle (C), as their first- or second-line treatment. The primary endpoint was G3+ANC in the first 29 days (C1). Secondary endpoints included AEs, efficacy, and serum thymidine kinase 1 (sTK1) activity. At data cutoff, fifty-four patients received a median of 13 cycles (range 2–6–43). The rate of G3+ANC was 21.3% (95% CI: 11.2–36.1%) without G4 in C1, and 40.7% (95% CI: 27.9–54.9%), including 38.9% G3 and 1.8% G4, in all cycles. The clinical benefit rate was 80.4% and 11.9% (10.43–NR) months, in the overall, endocrine sensitive (nPPS) (95% CI) was 19.75 (12.11–34.89), 33.5 (17.25–not reached (NR)), and C2D1 were, in the overall, endocrine sensitive or resistant population, respectively. High sTK1 at baseline, C1 day on C1D15 ( $p = 4.03 \times 10^{-4}$ ), indicating target inhibition. Rise in sTK1 predicted progression, with the median lead time of 5.95 (interquartile range: –206.25–0) days. Palbociclib, 5-days-on/2-days-off weekly, met its primary endpoint with reduced G3+ANC, without compromising efficacy. sTK1 is prognostic and shows promise in monitoring the palbociclib response. ClinicalTrials.gov: NCT03007979.

npj Breast Cancer (2022) 8:35; <https://doi.org/10.1038/s41523-022-00399-w>



# 2022 ASCO® ANNUAL MEETING

## **Circulating tumor DNA and serum thymidine kinase 1 activity matched dynamics in patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer treated in first-line with ribociclib and letrozole in the BioltaLEE trial**

**Grazia Arpino<sup>1</sup>, Giampaolo Bianchini<sup>2</sup>, Luca Malorni<sup>3</sup>, Alberto Zambelli<sup>4</sup>, Fabio Puglisi<sup>5</sup>, Lucia Del Mastro<sup>6</sup>, Marco Colleoni<sup>7</sup>, Filippo Montemurro<sup>8</sup>, Giulia Valeria Bianchi<sup>9</sup>, Ida Paris<sup>10</sup>, Giacomo Allegrini<sup>11</sup>, Stefano Tamperi<sup>12</sup>, Marina Elena Cazzaniga<sup>13</sup>, Michele Orditura<sup>14</sup>, Claudio Zamagni<sup>15</sup>, Donatella Grasso<sup>16</sup>, Matteo Benelli<sup>17</sup>, Maurizio Callari<sup>18</sup>, Antonina Benfante<sup>16</sup>, Michelino De Laurentiis<sup>19</sup>**

<sup>1</sup>Department of Medical Clinics and Surgery, Università Federico II, Napoli, Italy; <sup>2</sup>Department of Medical Oncology, Ospedale San Raffaele, Milano, Italy; <sup>3</sup>Department of Oncology and Translational Research Unit "Sandro Pitigliani", Ospedale di Prato, Azienda USL Toscana Centro, Prato, Italy; <sup>4</sup>U.S.C. Oncologia, Presidio Ospedaliero Papa Giovanni XXIII, Bergamo, Italy; <sup>5</sup>S.O.C. Oncologia Medica e Prevenzione Oncologica, IRCCS, Centro di Riferimento Oncologico, Aviano, Italy; <sup>6</sup>U.O.S.D. Breast Unit, IRCCS Ospedale Policlinico San Martino, Genoa, Italy; <sup>7</sup>Senologia Medica, IEO, Istituto Europeo di Oncologia, IRCCS, Milano, Italy; <sup>8</sup>Istituto di Candiolo, FPO, IRCCS, Candiolo, Torino, Italy; <sup>9</sup>SC Oncologia Medica 1, Fondazione IRCCS Istituto Nazionale Tumori Milano, Milan, Italy; <sup>10</sup>Department of Woman and Child Sciences, Fondazione Policlinico Universitario Agostino Gemelli, IRCCS, Rome, Italy; <sup>11</sup>U.O.C. Oncologia Medica, Presidio Ospedaliero Livorno, Livorno, Italy; <sup>12</sup>U.O. Oncologia, P.O. Ospedale degli Infermi – AUSL, Ravenna, Italy; <sup>13</sup>Phase 1 Research Unit & Oncology Unit, Azienda Socio Sanitaria Territoriale Monza & Milano Bicocca School of Medicine and Surgery, Monza, Italy; <sup>14</sup>U.O.C. Oncologia Medica e Ematologia, A.O.U. Università Degli Studi L. Vanvitelli, Napoli, Italy; <sup>15</sup>IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy; <sup>16</sup>Oncology, Novartis Farma SpA, Origgio, Italy; <sup>17</sup>Department of Oncology and Bioinformatics Unit, Ospedale di Prato, Azienda USL Toscana Centro, Prato, Italy; <sup>18</sup>CRUK Cambridge Institute, University of Cambridge Li Ka Shing Centre, Cambridge, United Kingdom; <sup>19</sup>IRCCS Istituto Nazionale Tumori Fondazione G Pascale, Napoli, Italy

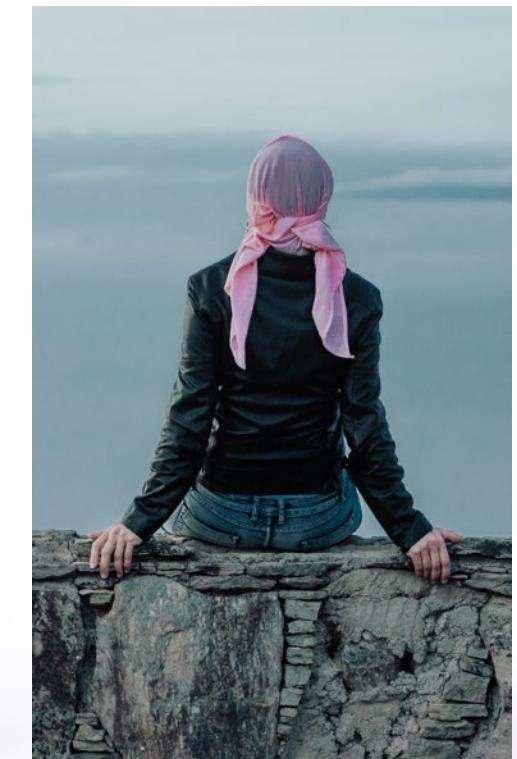
# TKa and ctDNA were the Chosen Blood-based Biomarkers for the BioltaLEE Study Design

- Phase IIIb single treatment study sponsored by Novartis and conducted at 47 Italian cancer centers
- 287 patients enrolled (241 patients with blood samples)
- HR+ metastatic breast cancer patients were treated with 1<sup>st</sup> line ribociclib + letrozole
- Goal of the study was to identify blood-based biomarkers that can predict how well a patient will do when treated with ribociclib
- Blood samples were drawn at baseline, day 15, and cycle 2 day 1
- Two biomarkers were analyzed independently by Novartis and the study investigators
  - ctDNA using a 533-amplicon Custom AmpliSeq HD Panel (39 BC-related genes) by Illumina
  - TK activity analyzed by DiviTum®TKa

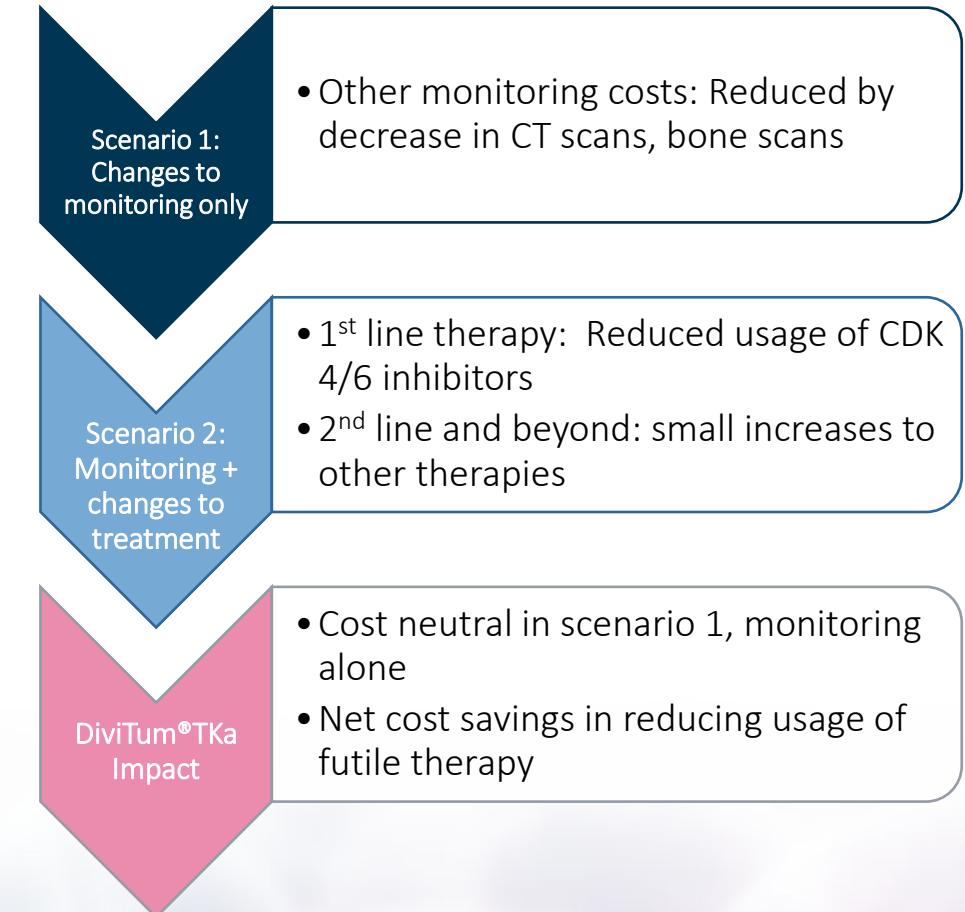
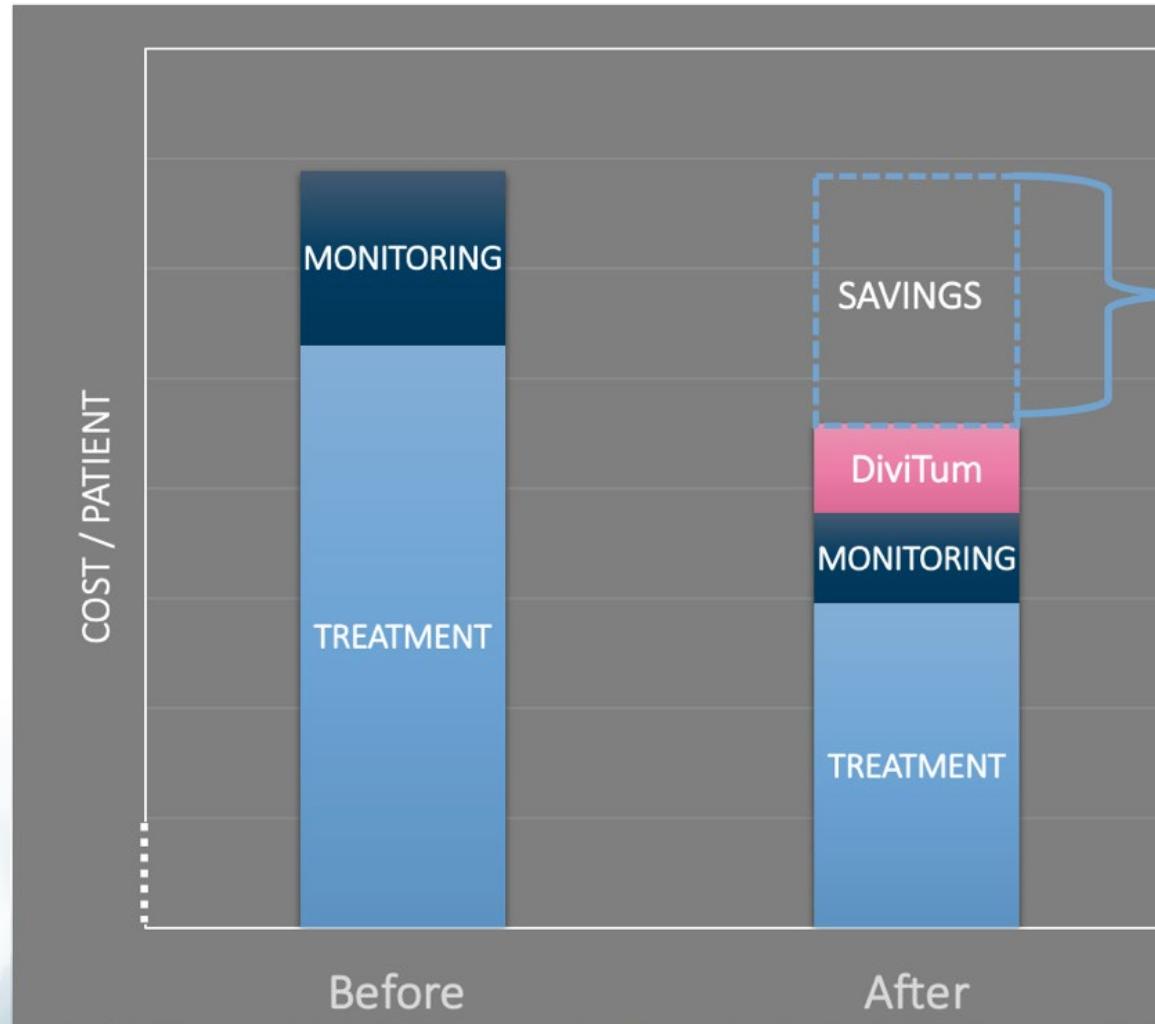


# Conclusions

- Baseline samples:
  - ctDNA and TKa are independently able to predict outcome for ribociclib + letrozole patients equally well
- On-treatment samples:
  - TKa dynamic patterns were better able to stratify patients according to outcome versus ctDNA dynamic patterns alone
- Combined on-treatment samples analysis:
  - TKa and ctDNA combined data show better correlation with outcome in patients not likely to respond to ribociclib + letrozole versus either biomarker alone
  - This further strengthens the evidence for DiviTum®TKa as a valuable biomarker for prediction and monitoring of CDK4/6i treatment response for metastatic breast cancer patients!



# Budget Impact Model Results: Addition of DiviTum®TKa to Care Would Lead to Net Savings of 3x the Spend



Strongly positive health economics for DiviTum®TKa with pricing modelled at \$400/test

# Agenda

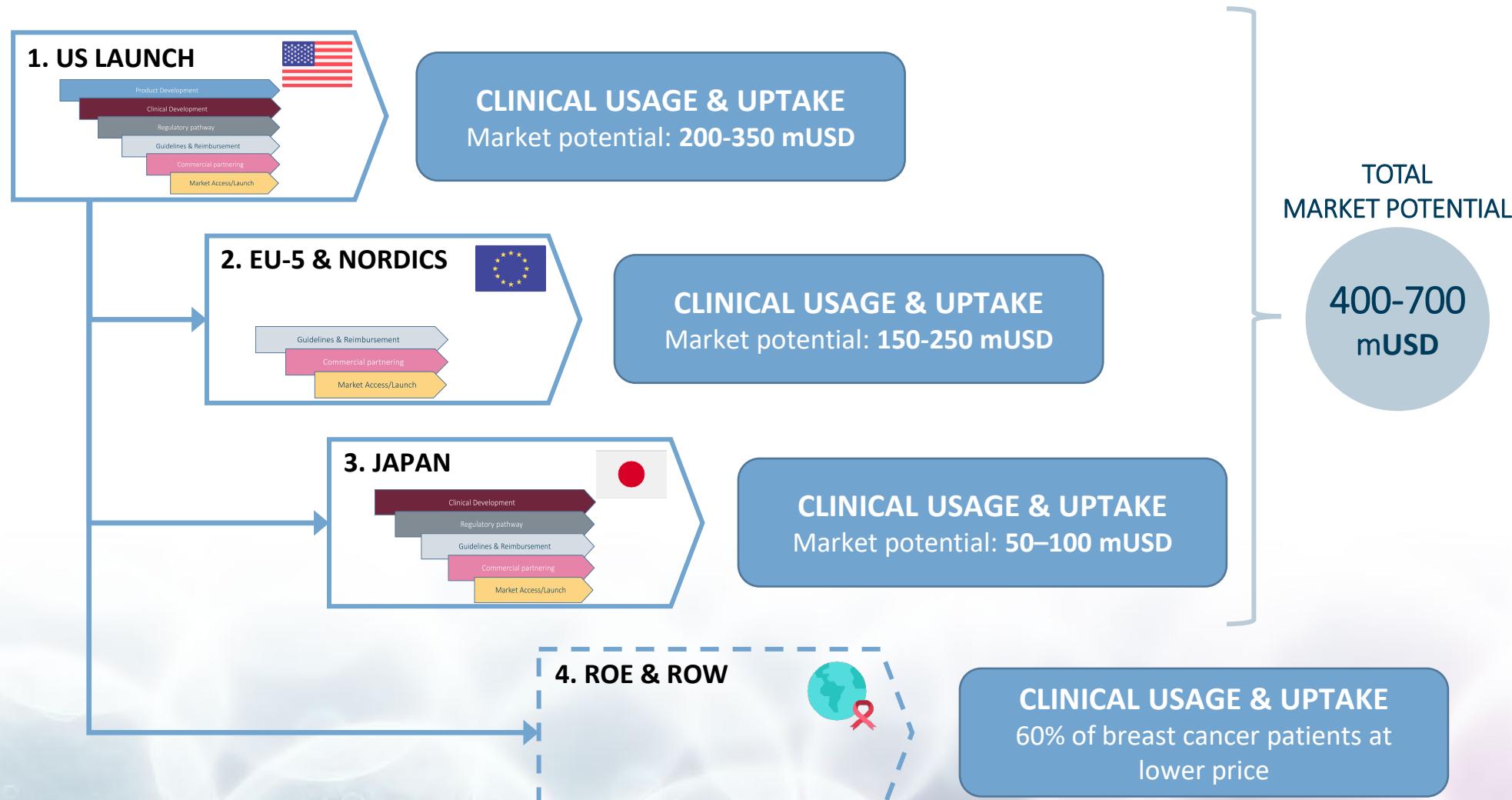
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# DiviTum®TKa – Key Commercialization Activities



# Geographical Roll-out Plan & Market Potential for DiviTum®TKa in Metastatic Breast Cancer



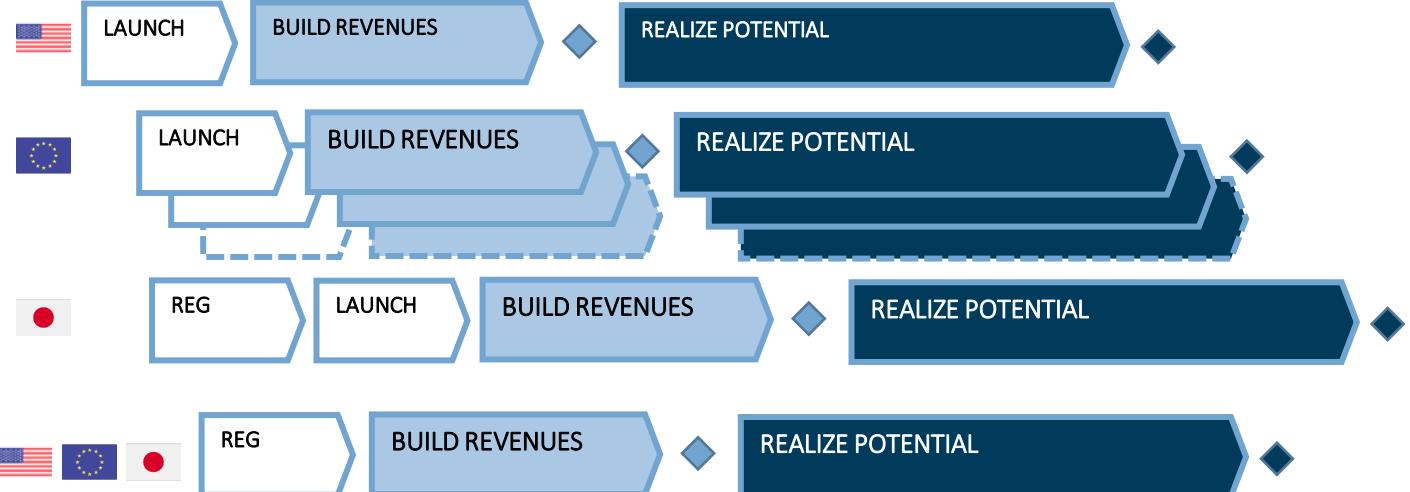
# Biovica Commercial Roadmap

## Legend

- 15% of market potential
- 50% of market potential

## MARKET POTENTIAL

### BREAST CANCER



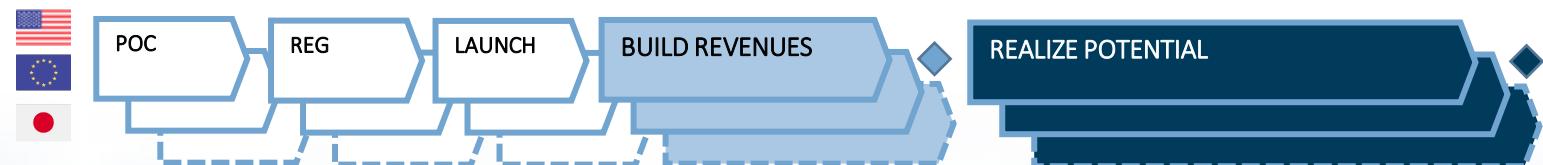
400-700  
mUSD/y

150-300  
mUSD/y

METASTATIC

LOCALLY ADVANCED

### NEW INDICATIONS



MM  
CRPC  
NSCLC

1.0-1.5  
bUSD/y



### CDx



CDx

50-100  
mUSD / per  
CDx

# Pharma Have Identified TKa as a Highly Relevant Tool for the Development of Cell Proliferation Inhibitor Drugs

Pharma-partner	Indication(s)	Drug (Rx)	Rx Study Phase	Agreement
1. TIER-2 <sup>2</sup> pharma (EU)	mBC (HR+, HER2÷). Patients resistant to CDK4/6i treatment.	CDK-inhibitor.	Phase IIa. Phase IIb. FDA fast track designation.	TESA <sup>3</sup>
2. TIER-2 <sup>2</sup> pharma (US)	mBC (HR+)	CDK-inhibitor	Phase I/II. Dose-escalation.	TESA <sup>3</sup> → MSA <sup>4</sup>
3. TIER-2 <sup>2</sup> pharma (US)	mBC and other solid tumors	CDK-inhibitor	Phase I	MSA <sup>4</sup>
4. TIER-2 <sup>2</sup> pharma (US)	Solid tumors	CDK-inhibitor	Phase I	RSA <sup>5</sup> /MSA <sup>4</sup>
5. TIER-2 <sup>2</sup> pharma (US)	Solid tumors	Rx's targeting key drivers of cancer cell growth	Phase I	KSA <sup>6</sup> →
6. TIER-1 <sup>1</sup> pharma (EU/US)	Breast, prostate and ovarian cancers	CDK-inhibitor	Phase I	KSA <sup>6</sup>
7. TIER-2 <sup>2</sup> pharma (US)	mBC (HR+), other solid tumors	CDK-inhibitor	Phase I/IIa	KSA <sup>6</sup>

<sup>1</sup>TIER-1: Large-sized Pharma; <sup>2</sup>TIER-2: Mid-sized Pharma

<sup>3</sup>TESA: technical Evaluation Service Agreement; <sup>4</sup>MSA: Master Service Agreement; <sup>5</sup>RSA: Research Service Agreement; <sup>6</sup>KSA: Kit Supply Agreement

# Experienced US team in place for a successful commercialization in US!

**Warren Cresswell**  
**President of Biovica Americas**

25-years of Diagnostic Experience in Medical Device (IVD 510(k) & PMA), CLIA Lab (LDT) Pharma.

Built Dx Orgs, Developed & Launched High Value Multi-Analyte Algorithm Based Dx Assays, and Implemented Effective Reimbursement Strategies.



**Kendon Richards**  
**Executive Director of Sales**  
25+ years of Pharmaceutical and Specialty Diagnostic Experience



**Dan Kiser**  
**Quality, Regulatory & Lab Operations**  
25-years Regulatory & Operations in CLIA, IVD, Medical Device & Pharma

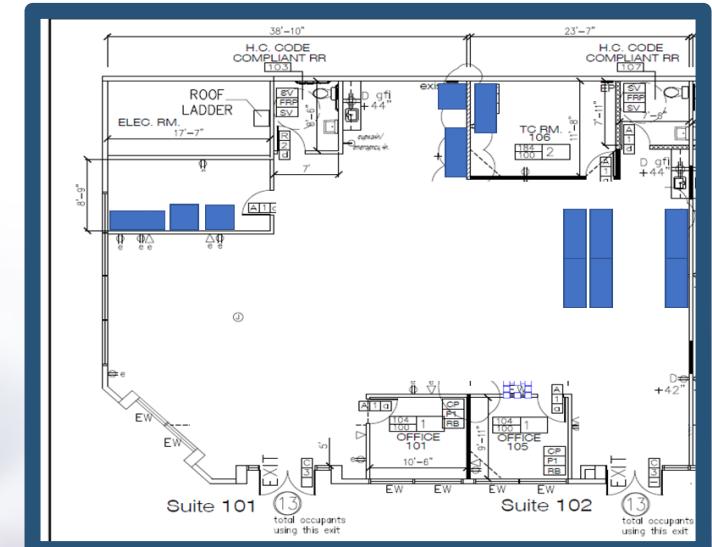


**Amy Williams, PhD**  
**Head of Clinical Development & Medical Affairs**  
20+ years of experience in oncology drug development

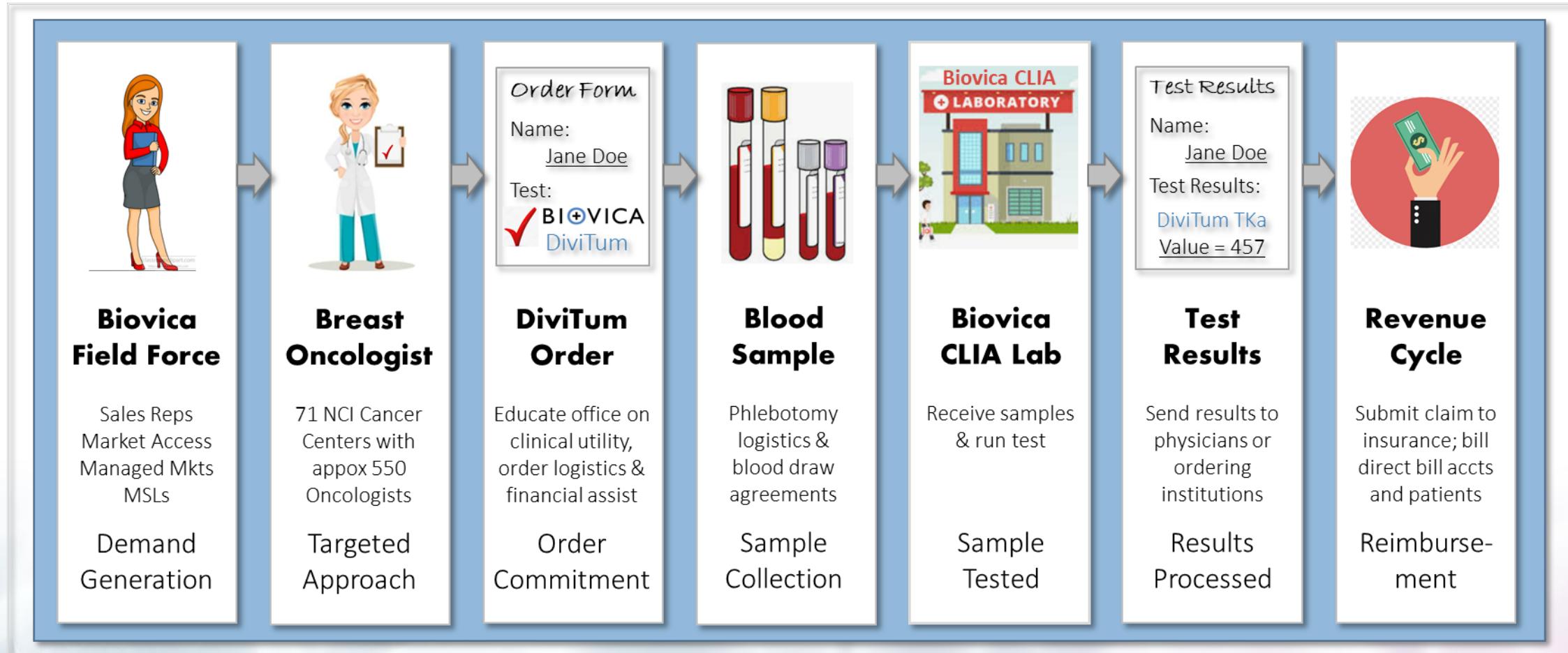
# Successful High Value Dx Companies Follow the CLIA Lab Go-To-Market Strategy

Managing *critical success factors* position the company for long-term sustainable growth:

1. *Stakeholder Relationships* - patient, physician and payer
2. *Reimbursement* – insurance coverage, value and utilization
3. *Access* – availability to all patients
4. *Data Development & Mining* – understanding product utilization, utility & correlation
5. *Sample Biobank* – deep analysis and fuel pipeline development



# The CLIA Lab Model Enables Management of the Entire Business Process

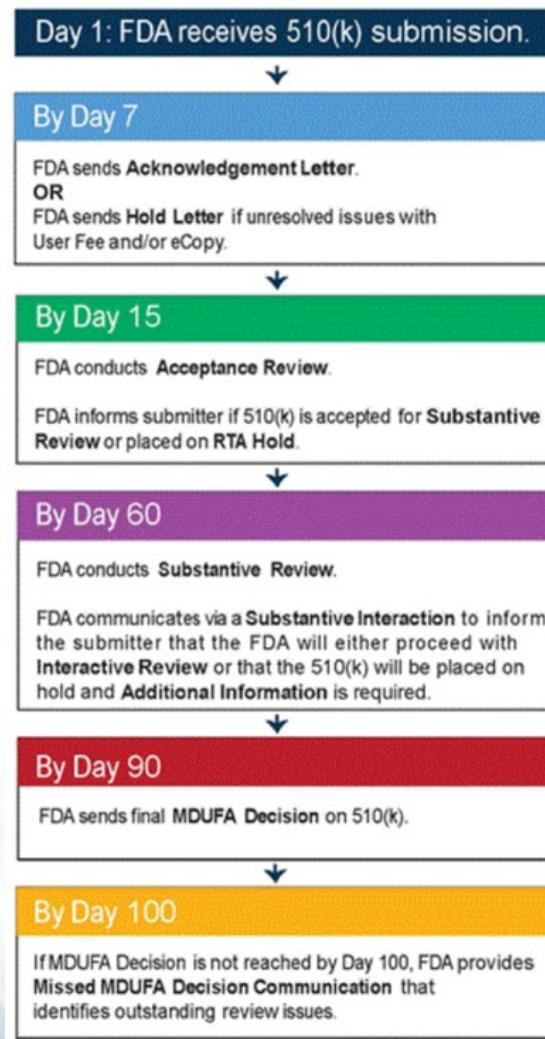


# Our Immediate Focus



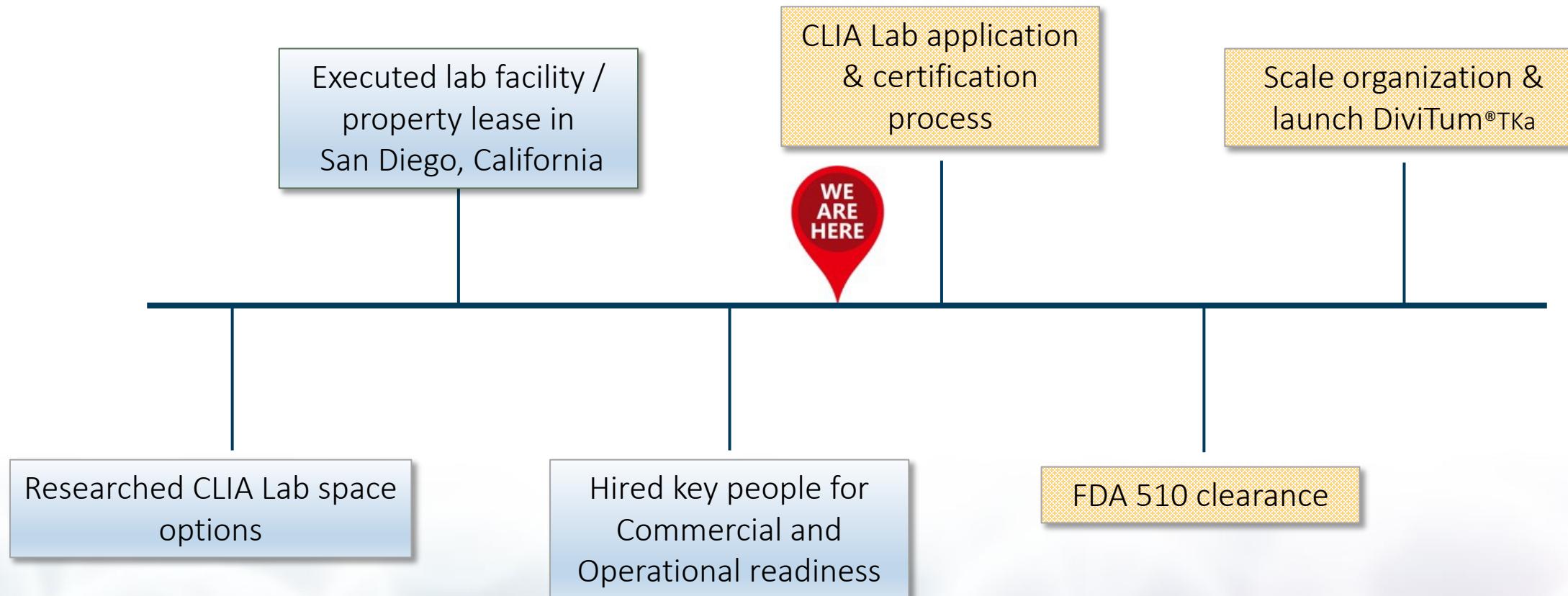
*Highly experienced candidates have been identified for nearly every US-based position*

# FDA 510(k) Application



- FDA 510(k) submission Q3 2020
- Positive interactive process with FDA, feedback in February
- Updated application, addressing all raised questions, was submitted on the 28<sup>th</sup> of April
- FDA has started their final assessment in Substantive review process
- Next step, MDUFA decision, expected in Q3

# US Operations Milestones



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# Management Team & Key People

**Anders Rylander**

CEO

Holdings: 3,575,640 A-shares,  
379,756 B-shares, 90,000 warrants**Cecilia Driving**

EVP CFO

Holdings: 20,000 B-shares,  
65,000 warrants**Helle Fisker**VP Commercial Europe  
Holdings: 20,000 warrants**Tomas Andersson**

VP Operations

Holdings: 40,000 warrants

**Joakim Arwidson**

VP Regulatory &amp; QA

Holdings: 20,000 warrants

**Henrik Winther, Ph.D.**

SVP Business Development

Holdings: 20,000 B-shares, 20,000 warrants

**Warren Cresswell**

President Americas

Holdings: 100,000 warrants

**Dan Kiser**

Head RA&amp;QA &amp; Lab Operations

Holdings: None

**Kendon Richards**

Executive Sales Director

Holdings: 15,000 warrants

**Amy Williams, Ph.D.**

Head of Clinical Dev. &amp; Medical Affairs

Holdings: 15,000 warrants

# Board of Directors

**Lars Holmqvist**

Chairman  
Holdings: 534,536 B-shares,  
100,000 warrants

**Annika Carlsson Berg**

Board Member  
Holdings: 50,000 warrants

**Maria Holmlund**

Board Member  
Holdings: 9,750 B-shares,  
75,000 warrants

**Henrik Osvald**

Board Member  
Holdings: 624,106 B-shares,  
50,000 warrants

**Jesper Söderqvist**

Board Member  
Holdings: 41,085 A-shares,  
38,200 B-shares, 75,000 warrants

**Jarl Ulf Jungnelius**

Board Member  
Holdings: 75,000 warrants

**Marie Louise Fjällskog**

Board Member  
Holdings: 45,000 warrants

**Anders Rylander**

Board Member & CEO  
Holdings: 3,575,640 A-shares,  
368,956 B-shares, 90,000 warrants

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# Summary & Milestones

- DiviTum®TKa addresses an important clinical unmet need
- DiviTum®TKa is supported by cancer KOL's and scientific collaborators globally
- These collaborations has generated strong clinical data
- Pharma collaboration and sales are developing positively
- First clinical launch will be for metastatic breast cancer.

## Upcoming milestones:

- Q3: 510(k) clearance
- Q4: US launch after 510(k) clearance
- 2023: Launch on 1<sup>st</sup> European market



# Share price development and turn over



# Financials Q4 2021/2022

- Net sales for the period amounted to SEK 1,082 (318) thousand. Fourth quarter sales are attributable to customers in the research market.
- Net sales for FY amounted to SEK 2,045 (2,077) thousand.
- Sales are only attributable to customers in the research market as product launch for clinical use in US are planned for later this year.



# Financials Q4 2021/2022

- The closing amount for cash & cash equivalents on 30 April 2022 was SEK 89,792 (145,364) thousand.
- Operating cash-flow for the period was 16,6 (9,0) MSEK
- The company is well capitalized and with the current capital, we expect our current cash to last for more than 12 months of operations.

