Providing answers for cancer patients





Curasight A/S
Interim report Q2 2023

In this document, the following definitions shall apply unless otherwise specified: "the Company" or "Curasight" refers to Curasight A/S, CVR no. 35249389.

# Global partnership agreement with Curium and promising results in brain cancer outcomes highlight Q2

As we conclude the second quarter of 2023, I am pleased to share with you the latest developments and progress at Curasight A/S. We have continued to build upon the successes of the past year, marked by intensive strategic work. In 2022, we updated our clinical strategy, pursued several promising indications, and established synergistic partnerships. As a result, we have advanced our position as a leading theranostic company and accelerated the development of our innovative solutions.

## Strategic milestones and transformational partnership

Q2 2023 represented one of the most strategically eventful quarters in Curasight's history with the momentous achievement being the partnership agreement with Curium, a global leader in the industry. This partnership represents a significant stride towards making our advanced technology available to prostate cancer patients worldwide. Under this agreement, Curasight will dedicate its efforts to developing our proprietary uTRACE® technology for use in prostate cancer, seeking regulatory approvals in both the USA and EU. In turn, Curium will assume the crucial responsibilities of commercial manufacturing and worldwide commercialization of uTRACE®. This collaboration serves as a validation of the robustness of our uTRACE® platform and its potential to positively impact a vast number of prostate cancer patients across the globe. We are excited about the prospects this partnership holds and the positive impact it will have on the lives of patients.

## Promising preclinical results with uTREAT® in brain cancer

During Q2, we received encouraging preclinical results for uTREAT® in treating aggressive brain cancer (glioblastoma). Our preclinical studies have demonstrated the effectiveness of uTREAT® in inhibiting tumor growth and significantly improving survival rates in a preclinical model of human aggressive brain cancer. The data unequivocally supports our strategic focus on developing uTREAT® as a viable treatment option for patients with aggressive brain cancer.

In these studies, animals receiving uTREAT® exhibited significantly inhibited tumor growth when compared to animals not treated with uTREAT®. Furthermore, the treated animals demonstrated improved survival rates, further underscoring the potential of uTREAT® as a powerful radioligand therapy for the treatment of aggressive brain cancer. These promising preclinical results have propelled us forward in advancing this transformative approach and hold immense promise for the future of cancer treatment.



## Positive phase II clinical trial outcomes with uTRACE® in brain cancer

Furthermore, we are pleased to share positive outcomes from the investigator-initiated phase II study using uPAR-PET (uTRACE®) in primary brain cancer. The study, carried out at Rigshospitalet in Copenhagen, was a milestone achievement, validating uTRACE® as a highly prognostic tool for progression-free survival and overall survival in patients with primary glioblastomas.

In the trial, 94% of glioblastomas (WHO grade 4 gliomas) were uPAR-PET positive. This underscores the validity of using uPAR-PET as a target for improved diagnosis and categorization in the context of aggressive brain cancer. The robust findings of this study strongly support our strategic intent to pursue a theranostic approach using uTRACE® and uTREAT® in glioblastoma patients.

#### **Solid financial position**

I am pleased to report that we have maintained a solid financial position during Q2, with a cash position of approximately DKK 32 million. This financial stability positions us well as we continue our development efforts and explore additional future funding options, including potential strategic partnerships.

Our dedication to innovation and strategic vision remains solid, and we are committed to accelerating our position as a theranostic company. Thank you for your continued trust in Curasight. Together, we envision a future where our theranostic solution transforms the lives of cancer patients worldwide.

Ulrich Krasilnikoff CEO, Curasight A/S

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## **Highlights Q2 and after**



On May 1, Curasight announced that it has entered into an exclusive global license and collaboration agreement with Curium Inc. – a global leader in radiopharmaceuticals – for the development and commercialization of uTRACE® for use in prostate cancer.

- Curasight to develop its proprietary uTRACE® PET imaging technology to obtain regulatory approval in EU and USA, with Curium responsible for manufacturing and commercialization.
- Curasight eligible for up to USD 70 mn in development and commercial milestones as well as double-digit royalties on sales on eventual commercialization.
- The agreement supports Curasight's strategy to leverage partnerships as it progresses its uPAR theranostic solution to diagnose and treat certain types of cancer.

**On May 31,** Ulrich Krasilnikoff and Andreas Kjær presented the company's Interim Report Q1 2023 at HC Andersen Capital and at Økonomisk Ugebrev.

**On June 7,** Curasight announced preclinical data demonstrating the effectiveness of uTREAT® in treating aggressive brain cancer (glioblastoma). The results from the study validate Curasight's strategic focus on developing uTREAT® as a viable treatment option for patients with aggressive brain cancer.

**On June 29,** Curasight announced positive results from the investigator-initiated phase II study using uPAR-PET (uTRACE®) in primary brain cancer. The study found that uPAR-PET/MR was a suitable target for the detection and prognosis of primary glioblastomas, the most common type of primary brain cancer.

By combining diagnostics with therapy - Curasight is on a mission to improve the lives of millions of people with cancer

**About Curasight** 

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## Curasight A/S in short

#### Curasight is a clinical phase II company based in

Copenhagen, Denmark. Curasight is the pioneer behind the novel uPAR Theranostics technology. The technology minimizes irradiation of healthy tissue by combining the targeted uTREAT® radiation therapy with the precise uTRACE® diagnostics. Several investigator-initiated phase II clinical trials have been completed or are currently undertaken.

PET-imaging, usually combined with CT as PET/CT is used to create images in which the biology of the disease can be studied. The principle is that a radiolabelled tracer is injected and bound to the tumor targets in the tissues, e.g. uPAR, after which the radioactivity can be located with the help of a PET-scanner. Together with his team, Professor Andreas Kjaer, developed a platform based on the radiolabelled PET-tracer uTRACE, Curasight's novel product that highlights the cancer biomarker uPAR. By injecting the patient with uTRACE, one can both image where the cancer is located and determine its level of aggressiveness.

uTRACE images cancer aggressiveness and invasive potential. By imaging this, Curasight's technology can diagnose and determine which therapeutic strategy should be pursued, e.g. if the patient needs treatment (e.g. surgery such as prostatectomy and/or radiotherapy) or not. In addition, uTRACE will be used for theranostics (principle of combined therapy and diagnostics) and precision medicine, selecting the right therapy to the right person at the right time, creating substantial benefits for both patients and the healthcare system.

#### uTRACE solution is expected to have major

advantages in the future evaluation of prostate cancer because it is expected to help determine what type of treatment – and in particular if surgery – is necessary.. Today most prostate cancer patients having prostatectomies performed are operated unnecessarily and most of these patients (up to 70 percent) experience some degree of side effects, such as impotence. The company believes that using Curasight's product and diagnosis could improve patient management. uTRACE is designed to provide a more accurate categorisation of a patient's tumor, supporting more tailored treatment plans allowing which can identify the necessary treatment at the right time.

Curasight's technology has been tested in a broad pipeline of 5 completed and is currently being investigated in 3 ongoing phase II clinical trials. According to the board's assessments, there is currently no other early-stage biotech company in the field of PET tracer development that has their technology tested in a broader portfolio of ongoing and planned clinical trials in

humans (whether investigator-initiated and academically sponsored or industry-sponsored trials), in many different cancer indications. In 2017 a phase I/Ila first-in-humans clinical trial with uTRACE was completed. In 2018 a phase IIb clinical trial with uTRACE in breast cancer; in 2020 a phase II study in prostate cancer; and in 2021/2022 two studies in head-and-neck cancer and neuroendocrine tumors, respectively, were completed.

#### (Diagnostics) uTRACE®

uPAR PET imaging with uTRACE\* for improved evaluation of cancer disease across several cancer types has been confirmed in mulitiple phase II clinical trails.

#### (Therapy) uTREAT®

radionuclide therapy is using uTRACE\* together with radiation therapy to locally irradiate cancer with limited irradiation of healthy tissue.

#### **uPAR Theranostic**

The combination of non-invasive PET imaging (Diagnostic) and targeted radionuclide therapy (Therapy) is together known at Theranostics.

Targeted radionuclide therapy (theranostics) may very well be the radiation therapy of the future. With the promising results obtained within diagnostics, Curasight now also pursues uPAR targeted radionuclide therapy using the uTRACE ligand but "armed" with short-range (1 mm) radiation therapy. In brief, the therapeutic ligand will be injected into a vein after which it will circulate and bind to all cancer cells in the body expressing uPAR and locally irradiate cancer with limited irradiation of healthy tissue. This concept represents a gentler form of radiotherapy compared to traditional external radiation therapy and is therefore by many considered the "radiation therapy of tomorrow". As PET imaging and radionuclide therapy are based on the same uPAR binding peptide, a uTRACE-scan can precisely predict where subsequent targeted radiation therapy will be delivered (theranostic principle).

#### **Business model**

Curasight aims to etablish uTRACE as an alternative to biopsies for risk stratification in prostate cancer. The geographic markets with the highest prevalence of these cancers are the U.S. and Europe. The Board and management of Curasight assess that the market potential for uTRACE as an integral component of a new and fast-growing market for active surveillance is substantial. Importantly, as a result of the unique

patient benefits and its compelling business model, Curasight expects uTRACE to catalyse the market for active surveillance. In brain cancer, Curasight expects its Theranostic solution with uTREAT to be game-changing in the way glioblastoma patients are diagnosed and treated. The orphan (rare) disease status and unmet medical need of this disease is expected to enable a "fast track" route to FDA approval. By establishing an advanced pipeline in multiple cancer indications, Curasight's board and management believe the Company will be an attractive candidate for partnership or out licensing agreement with Big Pharma. The area within Nuclear Molecular Imaging/Therapy has experienced strong traction with significant exit benchmarks over the recent period.

#### Critical path to regulatory approval

As a small and nimble company, Curasight seeks out highly specialised partners to secure the most optimal drug development. One important part of this strategy is to form collaborations with research and clinical contract organisations who are highly skilled in the field of both diagnostic and therapeutic radiopharmaceuticals. By forming partnerships with Contract Research Organisations (CROs), Contract Development Manufacturing Organisations (CDMOs), and Clinical Contract Organisations (CCOs) we ensure access to top development manufacturing expertise and capacity and skills in conducting good practice trial management and reporting. We are currently assessing the most optimal CDMO, CRO and CCO partners for our upcoming Phase 2 trial in prostate cancer with a 64Cu-labeled version of uTRACE® and look forward to bringing these companies on board in our development activities in the near future.

#### **Outlook for Curasight**

Curasight's first goal is to advance its lead products uTREAT (used for therapy) and uTRACE (used for diagnosing) to improve outcomes for the approx. 65,000 patients in the US and EU diagnosed annually with brain tumours. Accordingly, approximately 30,000 patients are diagnosed each year with high-grade glioma where the prognosis is very poor. Glioblastoma is a rare disease in both markets, qualifying for Orphan Drug Designation; moreover, because of the high unmet need, products targeting it are more likely to qualify for e.g. Priority Review, Breakthrough Therapy Designation, or Accelerated Approval.

Due to the very encouraging results from the finalised academic clinical phase-II study in Prostate Cancer, Curasight will look into how to accelerate the product development of uTRACE, a more flexible and non-invasive risk stratification tool compared to the present gold standard, for prostate cancer patients entering or being followed in active surveillance programs.

Furthermore, Curasight is looking into how to unfold further our platform and how to broaden the mission to realize the vast potential of uTRACE for diagnosing and uTREAT for targeted radionuclide therapy in other cancer types where uPAR is also expressed.

With reference to the recently published positive results from the investigator-initiated phase II studies performed by researchers at Rigshospitalet, using the uTRACE technology in both Neuroendocrine tumors (NET) and head and neck cancer, Curasight has decided also to further develop uTRACE and uTREAT for use in these two indications . This will be added to the existing program with uTRACE and uTREAT, where brain cancer is still the lead indication both within diagnostics and therapy.

#### **About neuroendocrine tumors**

Each year approximately 35,000 new cases are diagnosed in the US and EU. Due to the long survival of these patients, more than 400,000 patients are living with the disease in the US and EU. Neuroendocrine tumors are a rare form of cancer that occurs in glandular cells most frequently in the lining of the gastrointestinal tract or in the lungs, but the disease can in principle occur in all organs of the body.

#### About head and neck cancer

Head and neck squamous cell carcinoma is the 6th most common cancer worldwide with 890,000 new cases and 450,000 deaths in 2018. The incidence is anticipated to increase over the coming years.

#### Strategic partnerships

To support and accelerate the strategic business development, discussions are currently ongoing with a number of major pharma companies with a view to uncover opportunities and interest in uTRACE and uTREAT.

Key n	Key milestones 2023				
(i)	<b>H1 2023:</b> Results from pre-clinical study in brain cancer with uTREAT, (reported).				
(ii)	<b>H1 2023:</b> Results of phase IIb in Glioblastoma, (reported).				
(iii)	<b>H2 2023:</b> Results of preclinical study in additional cancer type with uTREAT.				
(iv)	<b>H2 2023:</b> Clinical trial application for uTRACE in Prostate cancer (EU).				



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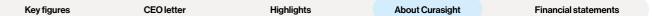
## Investigational Candidates in Clinical Development



Therapeutic platform

Planned studies

Completed investigator-initiated studies





## **Analyses**

CURASIGHT A/S



KapitalPartner initiated its commissioned research on August 2021, and has since then continuously monitored and analyzed Curasight's operations, products, markets, and competitors.

KapitalPartner's corporate page on Curasight is available at the following link: https://kapitalpartner.dk/curasight/



SEB initiated its commissioned research on June 18, 2021, and has since then continuously monitored and analyzed Curasight's operations, products, markets, and competitors.

SEB's corporate page on Curasight is available at the following link: https://research.sebgroup.com/corporate/companies/2853/overview



## **Corporate Information**

#### **Shareholders**

The table below presents the management's shareholdings in Curasight.

Name	Votes & capital (%)
AK 2014 Holding ApS <sup>1</sup>	30.24
UK Curacap ApS <sup>2</sup>	20.01
CHN Holding ApS <sup>3</sup>	12.11
Madsen Holding 2013 ApS <sup>4</sup>	4.57
LT 2003 ApS <sup>5</sup>	2.95
Per Falholt <sup>6</sup>	0.33
Charlotte Vedel <sup>7</sup>	0.20
Kirsten Drejer <sup>8</sup>	0.02
Hanne Damgaard jensen <sup>9</sup>	0.02

- 1. Owned by co-founder, CSO, and Board Member Andreas Kjaer
- 2. Owned by CEO and Board Member Ulrich Krasilnikoff
- 3. Owned by co-founder and Director Pre-Clinical Carsten H Nielsen
- 4. Owned by Co-founder and Director CMC, Jacob Madsen 5. Owned by Deputy Chairman of the Board, Lars Trolle
- 6. Chairman of the Board
- 7. Board Member
- 8. Board Member
- 9. Chief Development Officer (CDO)

#### The share

The shares of Curasight A/S were listed on Spotlight Stock Market on October 8, 2020.

The short name/ticker is CURAS, and the ISIN code is DK0061295797. As of June 30, 2023, the number of shares was 19,893,891 (19,893,891). All shares have equal rights to the Company's assets and results.

#### **Long-term incentive program**

Curasight has a long-term incentive program covering the financial years 2022-2025 with a total of 956,770 warrants covering the Company's Board of Directors, Executive Management and other key employees. For the Board of Directors, a total of 229,230 warrants are issued entitling the warrant holders to subscribe for up to a total of DKK 11,461.50 nominally worth of shares in the Company. The warrants are allocated between Per Falholt (chairman of the Board of Directors), Lars Trolle (vice-chairman of the Board of Directors) and Kirsten Aarup Drejer (member of the Board of Directors).

For the Executive Management and other key employees of the Company, a total of 727,540 warrants are issued entitling the warrant holders to subscribe for up to a total of DKK 36,377.00 nominally worth of shares in the Company. The warrants are allocated between

Ulrich Krasilnikoff (CEO), Andreas Kjær (CSO), Hanne Damgaard Jensen (CDO), Nic Gillings (Head of Quality Assurance and Regulatory Affairs) and Jacob Madsen (Director CMC).

#### Risks

A number of risk factors can affect Curasight's operations. It is therefore of great importance to consider relevant risks in addition to the Company's growth opportunities. For a detailed description of the risks attributable to the Company and its shares, please refer to the prospectus published by the Company in 2020. The prospectus is available on Curasight's website www.curasight.com.

#### **Accounting policy**

The interim report is presented in accordance with the provisions of the Danish Financial Statements Act (Årsregnskabsloven) for enterprises in reporting class B with application of provisions for a higher reporting class.

### The company has changed its accounting policies in the following areas:

Recognition of development costs as expense in the in the income statement. Previously, development costs were capitalized in the balance sheet. In future, development costs will be recognised as expenses in the income statement as management believes that this will provide a fairer presentation and it will be more comparative with other companies in the Pharma industry. The comparative figures have been restated in accordance with the new accounting policy.

#### **Auditor's review**

The interim report has not been reviewed by the Company's auditor.

Financial calendar	
Interim report Q3 2023	November 24, 2023
Interim report Q4 2023	February 22, 2024
Annual report 2023	February 22, 2024

## For further information, please contact: Ulrich Krasilnikoff, CEO

Phone: +45 22 83 01 60 E-mail: uk@curasight.com

## **Financial statements**

#### **Income statement**

Operating profit/loss before tax for the second quarter of 2023 amounted to kDKK -10 658 (-4 338). Operating profit/loss before tax for the first six months of 2023 amounted to kDKK -16 844 (-8 740).

External expenses for the second quarter amounted to kDKK -10 658 (-4 338) and staff expenses was kDKK -1 450 (-1 154). External expenses for the first six months of 2023 amounted to kDKK -16 842 (-8 384) and staff expenses was kDKK -2 799 (-2 174). External expenses comprise of clinical expenses, patent expenses, and business expenses.

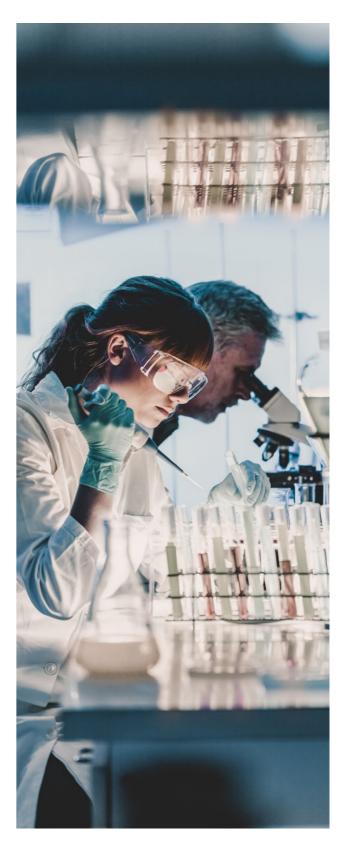
#### **Balance sheet**

Per June 30, 2023, the Company's balance sheet amounted to kDKK 46 331 (72 732). The assets consisted primarily of acquired IP-rights totalling kDKK 6 703 related to the development of uTRACE® and uTREAT® and cash amounted to kDKK 32 104. The equity and liabilities consisted primarily of an equity totalling kDKK 44 414.

#### **Cash flow**

Curasight's cash flow from operating activities in April-June 2023 amounted to kDKK -11 871. This post was primarily affected by the Company's loss for the period of kDKK -8 312.

Cash as of June 30, 2023, was kDKK 32 104 (60 046).







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## **Income statement**

(kDKK)	Q2 2023*)	Q2 2022*)	Q1-Q2 2023*)	Q1-Q2 2022*)	2022
Gross profit/loss	-9 029	-2 936	-13 685	-5 715	-11 487
Staff expenses	-1 450	-1 154	-2 799	-2 174	-4 697
Loss before depreciation, amortisation, write-downs and impairment losses	-10 479	-4 090	-16 484	-7 889	-16 184
Depreciation, amortisation and impairment of intangible assets and property,					
plant and equipment	-179	-248	-358	-495	-2 778
Profit/loss before financial income and expenses	-10 658	-4 338	-16 842	-8 384	-18 962
Financial costs	-	-170	-2	-356	-526
Profit/loss before tax	-10 658	-4 508	-16 844	-8 740	-19 488
Tax on profit/loss for the period	2 346	1 567	3 706	1 923	1 139
Net profit/loss for the period	-8 312	-2 941	-13 138	-6 817	-18 349

<sup>\*)</sup> Unaudited figures

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## **Balance sheet - Assets**

(kDKK)	2023-06-30*	2022-06-30*	2022-12-31
		1	
Intangible assets			
Acquired rights	6 703	2 022	7 041
Total intangible assets	6 703	2 022	7 041
Other fixtures and fittings, tools and equipment	119	159	139
Property, plant and equipment	119	159	139
Acquired shares in subsidary	0	7 423	0
Deposits	44	42	42
Total investments	44	7 465	42
Total non-current assets	6 866	9 646	7 222
Other receivables	7 259	2 914	1 203
Income tax receivable	102	126	1 298
Total receivables	7 361	3 040	2 501
Cash at bank and in hand	32 104	60 046	49 945
Total currents assets	39 465	63 086	52 446
Assets	46 331	72 732	59 668

<sup>\*)</sup> Unaudited figures





## **Balance sheet - Liabilities and equity**

(kDKK)	2023-06-30*	2022-06-30*	2022-12-31
Share capital	995	995	995
Retained earnings	43 419	68 089	56 557
Equity	44 414	69 084	57 552
Provision for deferred tax	0	716	0
Provisions	0	716	0
Prepayments received from customers	1 128	1 128	1 128
Trade payables	612	1626	763
Other payables	177	178	225
Total short-term payables	1 917	2 932	2 116
Total payables	1 917	2 932	2 116
Total liabilities and equity	46 331	72 732	59 668

<sup>\*)</sup> Unaudited figures

## **Equity - Q2\* 2023**

(kDKK)		Share Premium	Retained	
Changes in equity	Share capital	Account	earnings	Total
Share equity 1 April 2023	995	0	51 731	52 726
Net profit/loss for the period	0	0	-8 312	-8 312
Equity at 30 June 2023	995	0	43 419	44 414

<sup>\*)</sup> Unaudited figures

## **Equity - Q2\* 2022**

**CEO** letter

(kDKK)		Share Premium	Retained	
Changes in equity	Share capital	Account	earnings	Total
Share equity 1 April 2022	995	0	71 030	72 025
Net profit/loss for the period	0	0	-2 941	-2 941
Equity at 30 June 2022	995	0	68 089	69 084

**About Curasight** 

## **Equity - H1\* 2023**

(kDKK)		Share Premium	Retained	
Changes in equity	Share capital	Account	earnings	Total
Share equity 1 January 2023	995	0	56 557	57 552
Net profit/loss for the period	0	0	-13 138	-13 138
Equity at 30 June 2023	995	0	43 419	44 414

## **Equity - H1\* 2022**

(kDKK) Changes in equity	Share capital	Share Premium Account	Retained earnings	Total
Share equity 1 January 2022	995	0	74 906	75 901
Net profit/loss for the period	0	0	-6 817	-6 817
Equity at 30 June 2022	995	0	68 089	69 084

## **Equity - FY 2022**

(kDKK)	Share Premium		Retained	
Changes in equity	Share capital	Account	earnings	Total
Share equity 1 January 2022	995	0	74 906	75 901
Net profit/loss for the year	0	0	-18 349	-18 349
Equity at 31 December 2022	995	0	56 557	57 552

<sup>\*)</sup> Unaudited figures



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## **Cash flow statement**

(kDKK)	Q2 2023*)	Q2 2022*)	Q1-Q2 2023*)	Q1-Q2 2022*)	2022
Net profit/loss for the period	-8 312	-2 941	-13 138	-6 817	-18 349
Adjustments	179	604	358	848	2 165
Change in woring capital	-3 738	-878	-5 059	443	-645
Cash flow from operating activities before net financials	-11 871	-3 215	-17 839	-5 526	-16 829
Financial expenses	-	-170	-2	-356	-526
Cash flows from ordinary activities	-11 871	-3 385	-17 841	-5 882	-17 355
Corporation tax paid	-	-	-	-353	1 019
Cash flow from operating activities	-11 871	-3 385	-17 841	-6 235	-16 336
Purchase of intangible assets	-	-	-	-7 283	-7 283
Cash flows from investing activities	-	-	-	-7 283	-7 283
Cash capital increase	-	-	-	-	-
Cash captial reduction	-	-	-	-	-
Other equity entries	-	-	-	-	-
Cash flow from financing activities	-	-	-	-	-
Total cash flows for the period	-11 871	-3 385	-17 841	-13 518	-23 619
Cash, beginning of the period	43 975	63 431	49 945	73 564	73 564
Cash, end of the period	32 104	60 046	32 104	60 046	49 945
Cash and cash equivalents are specified as follows: Cash at bank and in hand	32 104	60 046	32 104	60 046	49 945
Cash, end of the period	32 104	60 046	32 104	60 046	49 945

<sup>\*)</sup> Unaudited figures

Q1 2023

## **Statement by the Board of Directors**

The Board of Directors provide their assurance that the interim report provides a fair and true overview of the Company's operations, financial position, and results.

København N, August 25, 2023 Curasight A/S

#### **Board of Directors**

Per Falholt, Chairman Chairman of the board Lars Trolle Board member

Kirsten Drejer Board member Charlotte Vedel Board member

Ulrich Krasilnikoff
Board member and CEO

Andreas Kjær Board member

Executive Board Ulrich Krasilnikoff CEO

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