

## Conditional Marketing Authorization in Europe Granted for Kinpeygo<sup>®</sup>

### Financial Summary For the Group

#### Key Figures

##### July 1 - September 30, 2022

- » Net sales amounted to SEK 260.1 million, whereof TARPEYO<sup>®</sup> net sales amounted to SEK 123.4 million, for the three months ended September 30, 2022. For the three months ended September 30, 2021 net sales amounted to SEK 198.2 million and no TARPEYO net sales were recognized.
- » Operating profit/(loss) amounted to (SEK 36.2 million) and SEK 7.9 million for the three months ended September 30, 2022 and 2021, respectively.
- » Earnings/(loss) per share before and after dilution amounted to (SEK 0.17) and SEK 0.21 for the three months ended September 30, 2022 and 2021, respectively.
- » Cash amounted to SEK 736.2 million and SEK 1,163.8 million as of September 30, 2022 and 2021, respectively.

##### January 1 - September 30, 2022

- » Net sales amounted to SEK 373.8 million, whereof TARPEYO net sales amounted to SEK 205.0 million, for the nine months ended September 30, 2022. For the nine months ended September 30, 2021 net sales amounted to SEK 198.2 million and no TARPEYO net sales were recognized.
- » Operating loss amounted to SEK 454.4 million and SEK 302.3 million for the nine months ended September 30, 2022 and 2021, respectively.
- » Loss per share before and after dilution amounted to SEK 7.72 and SEK 5.53 for the nine months ended September 30, 2022 and 2021, respectively.

### Significant Events in Q3 2022, in Summary

In July 2022, Calliditas announced that the European Commission (EC) granted Conditional Marketing Authorization for Kinpeygo for the treatment of IgA nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in EU. Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA Arzneimittel AG. Subsequently, in September 2022, Calliditas transferred its Conditional Market Authorization for Kinpeygo to its European commercial partner, STADA Arzneimittel AG, who will initially launch in Germany, with additional European countries to follow.

### Investor Presentation November 14, 2022 14:00 CET

Audio cast with teleconference, Q3 2022

Webcast: <https://ir.financialhearings.com/calliditas-therapeutics-q3-2022>

Teleconference: SE: +46850558350 UK: +443333009265 US: +16467224956



## European Launch and Approval

**On July 15th the European Commission issued the conditional marketing authorization for Kinpepygo, which marked the first time that any drug has achieved approval for this rare disease in EU.**

We immediately started the process of transferring the market authorization to our European partner, STADA Arzneimittel AG, in order to enable a launch in Europe as quickly as possible. STADA is initially launching the product in Germany, with other European countries to follow over time. With approval and commercial efforts now ongoing in both the US and Europe, we are looking forward to the regulatory process in China, where our partner, Everest Medicines, expects to receive NDA acceptance notice from NMPA this quarter. We are excited to support Everest as they work with regulators in China, who are expected to reach a decision regarding a potential approval in the second half of next year. If Nefecon is approved, this would be the first and only approved medication for the by Everest estimated 5m biopsy-proven IgAN patients in China.

In the US, we continue to build on our early commercial success. Net sales from TARPEYO grew by 94% when compared to Q2, resulting in net sales from TARPEYO of SEK 123.4 million (\$12.1m) for Q3. There is a growing number of nephrologists choosing to prescribe TARPEYO, with 166 new prescribers added in Q3, bringing total unique prescribers to 480 at the end of the quarter. We continue to see a continuous build of interest which mirrors the natural cadence of nephrology visits, which aligns with our expectations regarding this fairly silent, progressive disease. We expect to achieve net sales from TARPEYO for the year of between \$35 – 40m, which aligns with our internal plans for 2022. We also expect to see significant continued growth in 2023 as nephrologists become more familiar with the clinical data, access becomes more streamlined, and as topline data from the Part B of the NeflgArd trial becomes available.

As we continued to work on disease state education and built on our interactions with nephrologists, we became increasingly aware of the need to provide the broader community with a peer-reviewed overview of Part A of the NeflgArd data. We were therefore delighted to be able to have the Part A data published in *Kidney International* in October, 2022, as regulators also posted their review assessments. This data set, showing increasing reduction of proteinuria across the entire patient population during the 9 months on drug as well as significant continued reduction of proteinuria across the entire study population in the following 3 months when no drug was administered, showing a highly differentiated profile. The significance of this data was further confirmed by countless interactions at the American Society of Nephrology (ASN) Kidney Week in early November, where we had the opportunity to engage not only with KOLs but with the broader nephrology community treating IgAN patients. It was fantastic to see the high level of interest and excitement following the publication of our data and we were greatly encouraged by all of our interactions at ASN related to the interest in TARPEYO. The continued strong decline of proteinuria combined with the ability to immediately, as well as over the entire 12 month time period observed in Part A, virtually stabilize estimated glomerular filtration rate (eGFR) in patients with rapid disease progression was particularly interesting for physicians, since it provides early support for the

ability of TARPEYO/Kinpepygo to be disease modifying. We are looking forward to the read out of Part B of the NeflgArd trial in H1 of 2023 in order to report out the long-term impact of the treatment on patients' underlying kidney function.

Once patients have concluded the NeflgArd trial they are eligible to roll over into the Open Label Extension study (OLE). This is an open trial, with all patients receiving active drug, however it remains blinded as to whether patients were on active drug or placebo in the Phase 3 trial. Inclusion criteria are similar to the Phase 3 trial: proteinuria levels have to be  $\geq 1g/24h$  and eGFR has to be at least 30 ml/min. By the end of Q3, 180 patients had chosen to screen for OLE. Out of these, 74 had screened failed, with the predominant reason (61%) being lack of qualifying levels of proteinuria, with second most common reason being too low eGFR levels. Though exciting, no conclusions can be drawn from this blinded study, but it potentially further bolsters the approach of targeting the origin of IgAN to be disease modifying. The safety profile in the OLE trial is consistent with what was observed in the Phase 3 NeflgArd trial. We will continue to follow this patient population and look forward to unblinding the trial once the Phase 3 trial has been fully completed.

Following a good start of our setanaxib trials, we have seen a slower rate of site activations compared to plan, impacting patient recruitment rates. Biomarker data readout in our head and neck cancer study has therefore been pushed into 2023. The interim analysis of the TRANSFORM study is expected in the first half of 2024. This revised timing is still subject to recruitment rates developing as per our revised expectations, but we are hopeful that hospitals and clinics catching up on their backlog and improving their staffing levels will enable us to achieve our targets. We remain encouraged by the excitement and support of our investigators and the growing interest in NOX inhibitors, and setanaxib specifically, across the industry. We look forward to keeping you updated on the continued progress across our pipeline in our Q4 report, when we will also provide guidance for our estimated product sales for 2023.

**Renée Aguiar-Lucander, CEO**

# Our Commercial Product

Calliditas' lead product, which was granted accelerated approval by the US Food and Drug Administration (FDA) in December 2021 and conditional marketing authorization by the European Commission in July 2022, is a treatment specifically designed to target the origin of the autoimmune kidney disease IgA Nephropathy (IgAN).

IgAN is a serious progressive disease, in which up to 50% of patients end up at risk of developing end-stage renal disease (ESRD) within ten to twenty years. This product, which was developed under the name NEFECON, is approved under the brand name TARPEYO® in the United States and under the brand name Kinpeygo® in Europe.

## Disease Background

Although IgAN manifests in the kidney, the evidence indicates that it is a disease that starts in the distal part of the intestine, specifically in the ileum. Peyer's patches, which are concentrated within the gut-associated lymphoid tissue in the ileum, have been identified as a major source of mucosal-type IgA antibodies. Patients with IgA nephropathy have elevated levels of mucosal-type IgA, which – in contrast to the majority of the IgA in the blood - are predominately dimeric or polymeric and are galactose deficient. In IgAN patients, a combination of a genetic predisposition and of environmental, bacterial and dietary factors is presumed to lead to an increased production of these galactose-deficient IgA antibodies. This increased production, potentially in conjunction with increased intestinal permeability, leads to these secretory antibodies appearing in the blood.

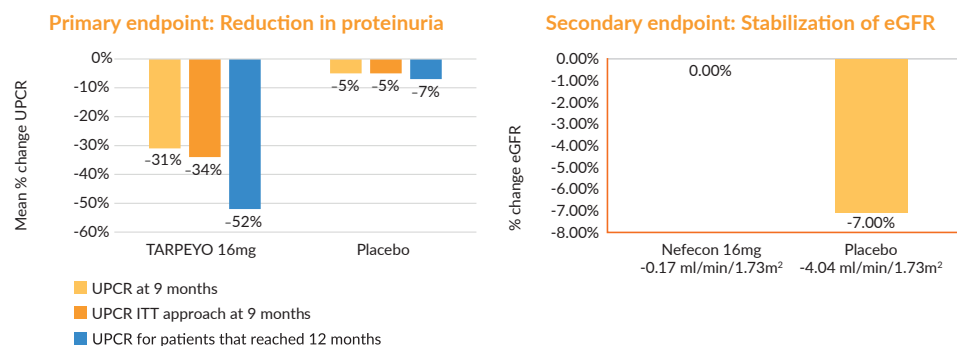
The galactose-deficient spot at the hinge region of the IgA antibodies is immunogenic when found in the circulation. It therefore generates an autoimmune response, attracting autoantibodies in the form of IgG or IgA which form pathogenic immune complexes that deposit in the glomeruli, the kidney's filtration apparatus. The trapped immune complexes initiate an inflammatory cascade which damages the kidney and ultimately destroys its filtration mechanism. This leads to slow, progressive deterioration of renal function, which in many patients ultimately results in the need for dialysis or kidney transplant.

<sup>1</sup>Barratt, J., Lafayette, R., Kristensen, J., et al. (2022). Results from part A of the multi-center, double-blind, randomized, placebo controlled NeflgArd trial evaluated targeted-release formulation of budesonide for the treatment of primary <https://doi.org/10.1016/j.kint.2022.09.017>

Calliditas' lead product is an oral, delayed release formulation of budesonide, a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism, resulting in limited systemic exposure. It was designed as a 4 mg delayed release capsule with an enteric coating so that it remains intact until it reaches the ileum. Each capsule contains beads coated with various polymers and budesonide designed to target the area with the highest concentration of Peyer's patches, with the intention of having a disease-modifying effect.

## Data

Calliditas' regulatory filings with the FDA and European Medicines Agency (EMA) were based on positive data from Part A of the NeflgArd pivotal Phase 3 study, which read out topline data in November 2020. Patients taking Nefecon showed a statistically significant 31% reduction in proteinuria from baseline vs 5% in the placebo cohort at 9 months; in the intention to treat (ITT) population, the reduction at 9 months of treated patients was 34%. Furthermore, for patients who had reached 12 months at the time of the data cut-off, the proteinuria reduction was 52%. The key secondary endpoint, eGFR, showed a treatment benefit of 7% versus placebo at 9 months, reflecting stabilization in the treatment arm and a 7% decline of eGFR in the placebo arm (p=0.0029). This reflected an absolute decline of 4.04 ml/min/1.73m<sup>2</sup> in the placebo group over 9 months compared to a 0.17 ml/min/1.73m<sup>2</sup> decline in the treatment arm. The trial also demonstrated that Nefecon was well-tolerated. This data has now been published in a peer reviewed article in *Kidney International*.<sup>1</sup>



## Our Commercial Product (cont.)

### Approval in the US

The product is approved under the accelerated approval pathway under the brand name TARPEYO® in the United States. TARPEYO is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally defined as a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/g. It is the first and only FDA-approved treatment for IgA nephropathy.

Calliditas has been granted orphan drug designation for the treatment of IgAN in the United States and is commercializing TARPEYO in the United States on its own.



**TARPEYO™**  
(budesonide) delayed release capsules • 4 mg

### Approval in EU

In July 2022, the product was granted conditional marketing authorization by the European Commission under the brand name Kinpeygo® for the treatment of IgAN in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in EU.

Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA Arzneimittel AG with whom Calliditas entered into a license agreement in July 2021. The deal with STADA to register and commercialize Kinpeygo in the European Economic Area (EEA) member states, Switzerland and the UK was valued at a total of EUR 97.5 million, plus royalties. Under the terms of the agreement, Calliditas received an initial upfront payment of EUR 20 million upon signing and have received additional EUR 12.5 million for conditional marketing authorization and commercialization. Calliditas is further entitled to up to an additional EUR 65 million in future payments linked to pre-defined regulatory and commercialization milestones. STADA is also due to pay tiered royalties on net sales expressed as a percentage between the low twenties and the low thirties.

Following the transfer of the conditional marketing authorisation, STADA launched Kinpeygo in Germany, with additional European countries to follow. In Germany it is estimated that 3.1 people per 100,000 develop IgAN each year.

### Greater China, Singapore and South Korea

Calliditas also has a commercial partner in China and Singapore, having entered into a license agreement to develop and commercialize NEFECON for IgAN in those markets with Everest Medicines in 2019. Calliditas received an initial upfront payment of USD 15 million upon signing, as well as future payments linked to development, regulatory and commercialization milestones up to an additional USD 106 million, plus royalties. In March 2022, this agreement was expanded to include South Korea. Everest Medicines will look to file with regulators in China in the fourth quarter 2022, with a view to target potential approval in the second half of 2023.

# Building on a Successful Commercial Launch

In our third quarter of sales of TARPEYO®, the commercial team has built on the successful strides made since our first sale in late January. We continue to engage with healthcare providers (HCPs), payers and patients and remain encouraged by their enthusiasm for our product.

Our specialty sales team has continued to build on the strong results in the first half of the year, recording net sales for the third quarter of USD 12.1 million (SEK 123.4 million). An expansion of our sales force was decided in June and conducted during the third quarter, as we brought our sales team up to 60 specialty sales representatives. We expect that the impact of the expansion should be reflected to some degree in Q4, but predominantly in early 2023 as these representatives begin bolstering our reach and frequency of contact to our target audience.

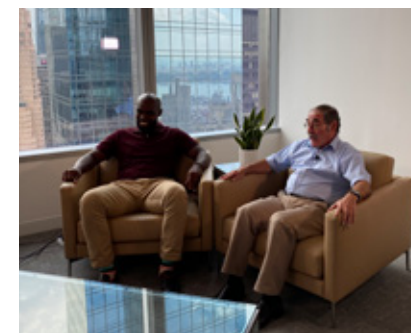
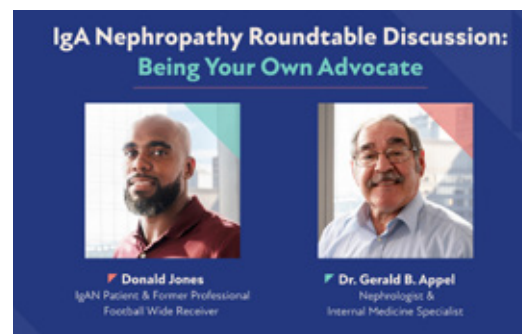
Since the launch of TARPEYO in late January to the end of September, there have been a total of 730 patient enrollments, with enrollments in Q3 amounting to 281, reflecting a strong September month after the summer period of July and August. In terms of new prescribers, Q3 continued to see broad interest from nephrologists with unique prescribers at the end of September amounting to 480, reflecting an increase of 166 new prescribers during the third quarter. In addition to our sales force expansion, we expect continued growth based on our extensive interactions and large presence at Kidney Week/ASN as well as the publication of the data from the NeflgArd trial.

The process of achieving 85-90% reimbursement coverage for TARPEYO is now almost complete, with the channel mix still containing approximately 70-75% commercial insured patients. The majority of the remaining 25-30% are government subsidized insured patients, which include Medicare and Medicaid. Enrolled patients whose process has reached a conclusion continued to have an impressive reimbursement approval rate of more than 80%. While the average time for prescription fill is already less than 30 days for those prescriptions which have been successfully concluded, the commercial team continues to focus to improve this rate to in an effort to exceed industry standards.

Our marketing team has continued to drive promotional efforts across various channels to boost the product's profile and ensure uptake of TARPEYO. Awareness of TARPEYO remains high with unaided and aided awareness greater than 70% and 80%, respectively. In addition, market research conducted with nephrologists continues to demonstrate the effectiveness of our educational and promotional programs, with peer-to-peer programs continuing to emphasize both disease education and the strong clinical benefits of TARPEYO and we look forward to launching several additional educational initiatives over the next several months.

All patients are guided through the enrollment and procurement process with the support of our patient services program, TARPEYO Touchpoints™, which assists physicians and patients via a designated Rare Pod Team – including nurses, pharmacists, and a fulfillment and distribution team. This quarter, the TARPEYO Touchpoints team was expanded, adding additional care navigators to support the increasing numbers of patients being part of the program, with the aim of continuing to provide high engagement and service for every patient.

Calliditas remains engaged with the IgA nephropathy patient audience via our patient advocacy efforts and outreach. In July, Calliditas was a lead sponsor at the IGA Nephropathy Foundation's SPARK 2022 symposium, continuing our long-standing support of the foundation in its efforts to educate, support and engage the IgAN patient and caregiver community. Also during the quarter, we launched an unbranded patient ambassador program and went live with a patient advocacy video featuring former NFL player Donald Jones and leading KOL Dr Gerald Appel. We continue to work closely with IgAN patient ambassadors to raise awareness of this disease and the impact it has on patients and caregivers via multiple channels, including TV and radio networks.



Our medical affairs team has continued to ensure we have a presence at all relevant symposia and congresses, with the annual American Society of Nephrology kidney week in November as one of the most important of the year. During the past quarter, our Chief Medical Officer Richard Phillipson participated on a key panel discussion alongside the FDA's Deputy Director of the Division of Cardiology & Nephrology, Aliza Thompson, at the Annual Rare & Genetic Kidney Disease Drug Development conference. Calliditas' medical affairs team has continued to partner with and attend relevant regional and local meetings to engage in peer-to-peer group and individual education efforts.

# Pipeline: NOX Inhibitor Platform

Calliditas' pipeline contains development programs based on a first in class, novel NOX inhibitor platform. The lead compound, setanaxib, is the first NOX inhibitor to reach the clinical trial stage and is a selective NOX 1 and NOX 4 inhibitor. Calliditas is presently running trials with setanaxib in Primary Biliary Cholangitis (PBC) and in Squamous Cell Carcinoma of the Head & Neck (SCCHN).

## NOX Enzymes

NOX enzyme inhibitors are a set of promising novel experimental drugs in a new therapeutic class, recognised by the WHO since 2019 when it approved "naxib" as a new stem. Nicotinamide adenine dinucleotide phosphate (NADPH) oxidases, otherwise known as NOX enzymes, are the only known enzymes that are solely dedicated to producing reactive oxygen species (ROS) as their primary and sole function. They are transmembrane enzymes that transfer electrons from NADPH in the cytoplasm across the cell membrane, which results in the formation of ROS.

At appropriate concentrations, ROS have essential functions in cellular signaling processes, but disruption of the redox homeostasis has been implicated in multiple disease pathways. Setanaxib inhibits NOX1 and NOX4, enzymes which are implicated in inflammation and fibrosis pathways.

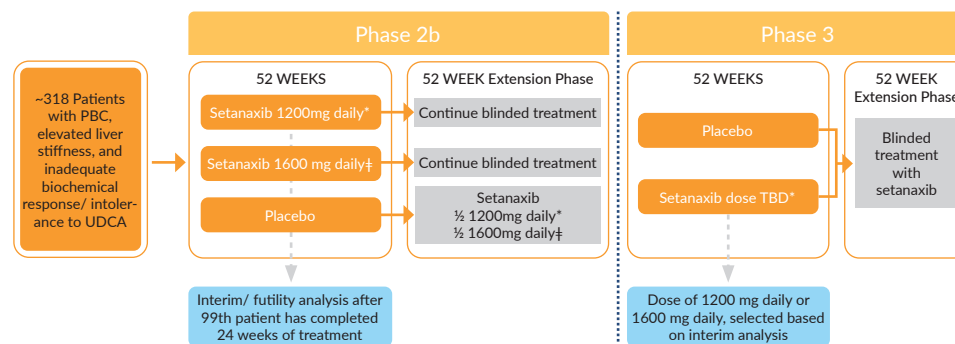
## Setanaxib in Primary Biliary Cholangitis

PBC is a progressive and chronic autoimmune disease of the liver that causes a cycle of immune injury to biliary epithelial cells, resulting in cholestasis and fibrosis. It is an orphan disease and, based on its known prevalence rates, we estimate that there are approximately 140,000 patients in the US, where the annual incidence ranges from 0.3 to 5.8 cases per 100,000.

Ursodeoxycholic acid, a generic drug also known as ursodiol or UDCA, and obeticholic acid, known as Ocaliva, are the only FDA- and European Commission-approved treatments for PBC. However, despite these treatment options, there is still an unmet medical need among PBC patients, in particular when it comes to important quality of life outcomes.

Calliditas has initiated a 52-week, randomized, placebo-controlled, double-blind, trial with an adaptive Phase 2b/3 design. Calliditas announced that the first patient was randomised in the TRANSFORM study on 15th February 2022.

Setanaxib will be administered to approximately 318 patients with PBC and elevated liver stiffness as well as intolerance or inadequate response to UDCA in a global trial conducted in up to 150 investigational centres. The primary endpoint is ALP reduction, with key secondary endpoints including change in liver stiffness and effect on fatigue and pruritus (itching). Following favorable safety data from a Phase 1 study, this trial will evaluate two dosing regimens of 1200mg/daily and 1600mg/daily. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in the first half of 2024, subject to recruitment rate, and will determine which dose of setanaxib will be used for the Phase 3 part of the study. In August 2021, Calliditas received FDA Fast Track Designation for setanaxib in PBC.



\*Dose of 1200 mg daily administered as 800 mg AM and 400 mg PM

‡Dose of 1600 mg daily administered as 800 mg AM and 800 mg PM



# Pipeline: NOX Inhibitor Platform

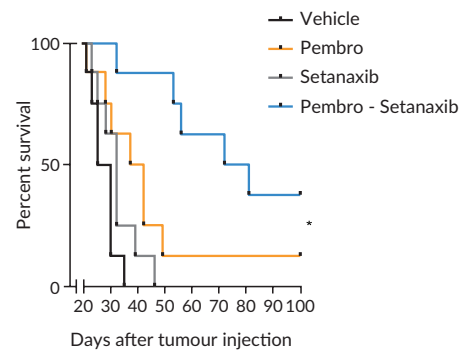
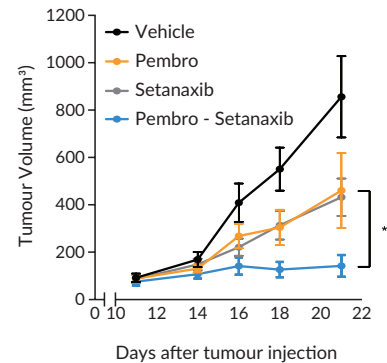
## Setanaxib in Squamous Cell Carcinoma of the Head & Neck

Calliditas also intends to evaluate setanaxib in head and neck cancer, building on promising in vivo preclinical data that suggests that setanaxib could function as an adjunct therapy to immunology therapies. The response to immuno-oncology therapies can be affected by the tumour microenvironment, in particular by the numbers of tumour-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs) in the tumour. A relationship between cancer associated fibroblasts (CAFs) and prognosis in Squamous Cell Carcinoma of the Head & Neck (SCCHN) has been established.

NOX4 is highly over-expressed in CAFs and drives myofibroblastic activation within tumours, shielding them from CD8+ TILs. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunct therapy. There is increasing use of pembrolizumab as 1st line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%).

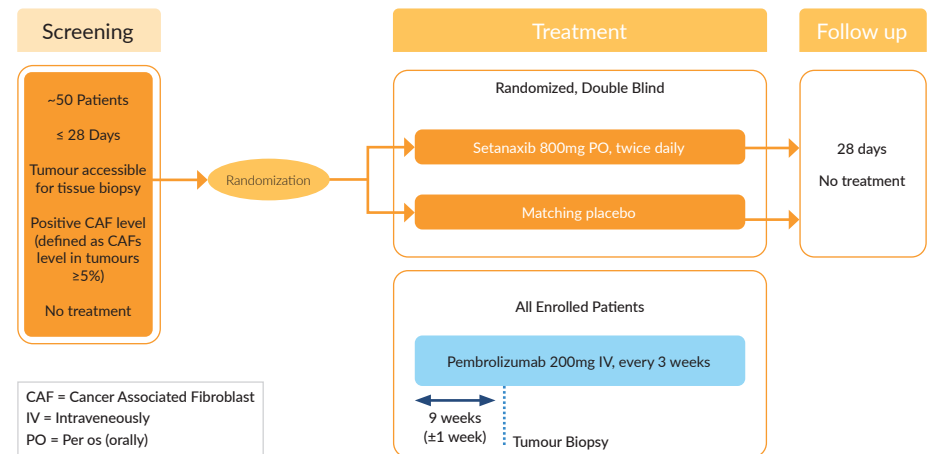
Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:

- Improved penetration of TILs into the centre of the tumour
- Slowing of tumour growth and improved survival



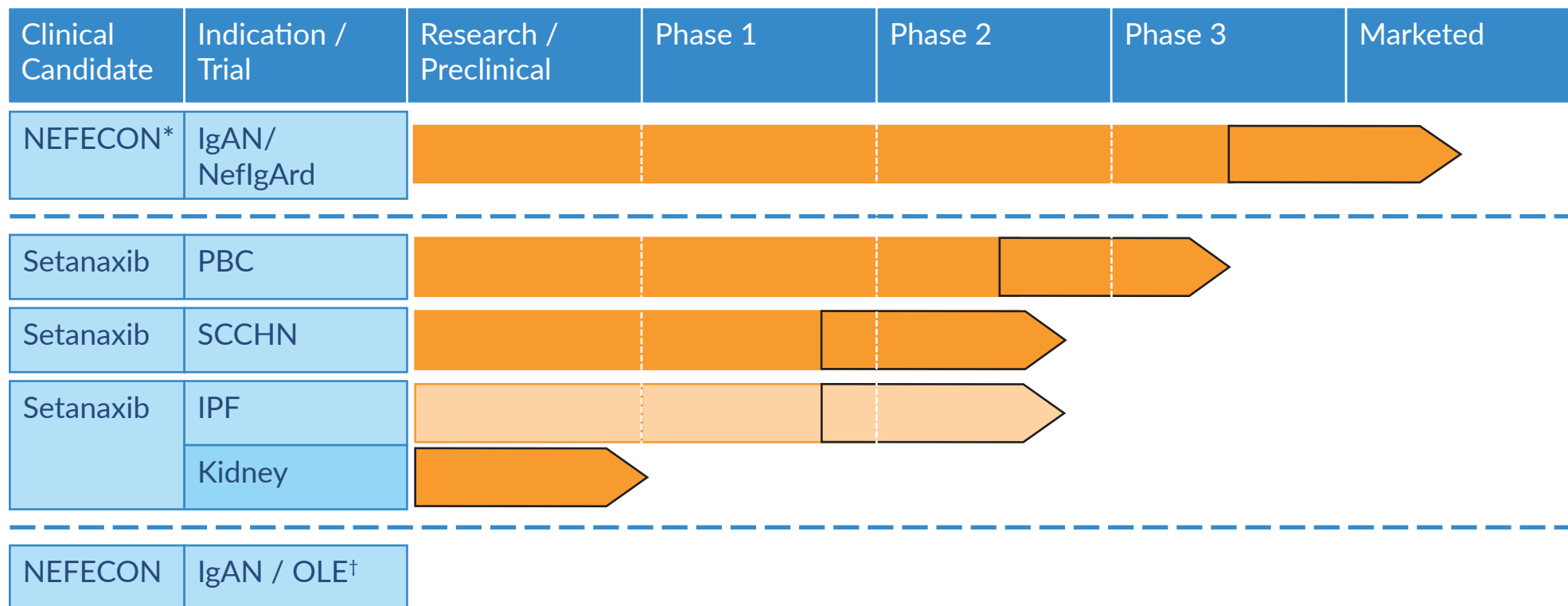
## Proof-of-concept study in head and neck cancer

Calliditas is conducting a Phase 2 proof-of-concept study in patients with head and neck cancer, which will investigate administration of setanaxib in conjunction with immunotherapy targeting CAFs.



The study will likely involve approximately 50 patients. The first patient was randomised in Q2 2022, with an interim biomarker readout expected in 1H 2023.

# Our Pipeline



Depicts ongoing/planned clinical trial stage: Depicts Investigator Led Trial:

† Open Label Extension, intended to primarily support treatment-related considerations.

\* Approved under accelerated approval in the USA under the tradename TARPEYO. TARPEYO (budesonide) delayed release capsules is a prescription medicine used to reduce levels of protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at high risk of rapid disease progression, generally UPCr ≥ 1.5g/g. Approved under conditional marketing authorisation in EU under the tradename Kinpeygo.

Setanaxib is also being evaluated in an investigator led trial in DKD (Diabetic Kidney Disease).



# Significant Events

## Significant Events During the Period January 1 – September 30, 2022

- In January 2022, Calliditas announced the commercial availability and initial sales of TARPEYO (budesonide), the first and only FDA approved treatment for IgA nephropathy, indicated for reduction of proteinuria in adults with primary IgA nephropathy (IgAN) at risk of rapid disease progression, generally considered a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$ g/g. Calliditas is committed to working with payers and healthcare providers across the United States to help ensure that all patients prescribed TARPEYO have access to it. To assist patients and their healthcare providers who would prescribe TARPEYO, Calliditas has launched a comprehensive patient support program, TARPEYO Touchpoints™. This program offers services, assistance, and resources designed to help patients access treatment as easily as possible.
- In February 2022, Calliditas announced that the first patient had been randomized in the company's pivotal phase 2b/3 TRANSFORM study in patients with primary biliary cholangitis (PBC). The TRANSFORM trial is a 52-week, randomized, placebo-controlled, double-blind, adaptive Phase 2b/3 trial. It will initially investigate the effect of setanaxib 1200 mg/day and 1600 mg/day versus placebo on alkaline phosphatase (ALP) reduction in patients with PBC and with elevated liver stiffness and intolerance or inadequate response to ursodeoxycholic acid (UDCA). Key secondary endpoints include change from baseline in liver stiffness, assessed by transient elastography (FibroScan®), and change from baseline in fatigue. An interim analysis will be conducted once the 99th randomized patient has completed the Week 24 visit, which is expected in the first half of 2024, subject to recruitment rate. The interim analysis outcome will determine which of the two doses will be selected for the Phase 3 portion of the trial.
- In March 2022, Calliditas announced that the company had expanded its licensing agreement with Everest Medicines to extend the territory covered to include South Korea. The extension results in an upfront payment of USD 3 million to Calliditas as well as additional payments and royalties related to future potential approvals and commercialization of Nefecon in South Korea. Calliditas and Everest Medicines entered into a license agreement in 2019 to develop and commercialize Nefecon in Greater China and Singapore for the chronic autoimmune kidney disease IgA Nephropathy (IgAN).
- In May 2022, Calliditas announced that the first patient has been randomized in the Group's proof-of-concept Phase 2 study in patients with squamous cell carcinoma of the head and neck (SCCHN) with the NOX 1 and 4 inhibitor, setanaxib.
- In May 2022, Calliditas announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the granting of a conditional marketing authorisation for Kinpeygo for the treatment of primary immunoglobulin A (IgA) nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/gram.
- In May 2022, the Annual General Meeting (AGM) of Calliditas was held and, among other things, the AGM resolved on the election of Henrik Stenqvist and Elisabeth Björk to the Board of Directors and the establishment of a U.S. At-the-Market framework of up to a maximum of 5,908,019 shares, pursuant to which Calliditas may, at its option, sell American Depositary Shares ("ADSs") in the United States at market price, from time to time, in "at the market" transactions on The Nasdaq Global Select Market.
- In July 2022, Calliditas announced that the European Commission (EC) granted conditional marketing authorization for Kinpeygo for the treatment of IgA nephropathy (IgAN) in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/gram. Kinpeygo is an orphan medicinal product and became the first and only approved treatment for IgAN in EU. Kinpeygo will be marketed in the European Economic Area (EEA) exclusively by STADA Arzneimittel AG. Subsequently, in September 2022, Calliditas transferred its Market Authorization for Kinpeygo to its European commercial partner, STADA Arzneimittel AG, who will initially launch in Germany, with additional European countries to follow.

# Key Figures

(SEK in thousands, except per share amount or as otherwise indicated)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Net sales	260,056	198,167	373,837	198,167	229,347
Research and development expenses	(102,877)	(92,098)	(312,510)	(257,194)	(357,485)
Research and development expenses/Total operating expenses in %	35%	48%	38%	51%	47%
Operating profit/(loss)	(36,227)	7,856	(454,438)	(302,323)	(524,456)
Profit/(loss) before income tax for the period	(15,958)	6,480	(419,483)	(294,906)	(513,373)
Earnings/(loss) per share before dilution (SEK)	(0.17)	0.21	(7.72)	(5.53)	(9.84)
Earnings/(loss) per share after dilution (SEK)	(0.17)	0.21	(7.72)	(5.53)	(9.84)
Cash flow used in operating activities	(124,725)	(33,245)	(541,383)	(300,334)	(461,588)

(SEK in thousands, except per share amount or as otherwise indicated)	September 30,		December 31,
	2022	2021	2021
Total registered shares, including shares held by Calliditas, at the end of the period	59,157,587	52,341,584	52,341,584
Equity attributable to equity holders of the Parent Company at the end of the period	725,936	1,255,047	1,008,281
Equity ratio at the end of the period in %	48%	73%	69%
Cash at the end of the period	736,161	1,163,818	955,507

# January – September 2022

## Revenue

Net sales amounted to SEK 260.1 million for the three months ended September 30, 2022, and for the nine months ended September 30, 2022, net sales amounted to SEK 373.8 million. For the three and nine months ended September 30, 2021, net sales amounted to SEK 198.2 million, respectively. Net sales for the three and nine months ended September 30, 2022, primarily originates from net sales of TARPEYO in the U.S., which amounted to SEK 123.4 million for the three months ended September 30, 2022, and SEK 205.0 million for the nine months ended September 30, 2022. Further, for the three and nine months ended September 30, 2022, net sales also consisted of SEK 135.0 million in milestone fees from STADA for the conditional approval and commercialization of Kinpeygo in Europe. In addition, for the nine months ended September 30, 2022, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea which amounted to SEK 28.8 million. For additional information see Note 4.

## Cost of Goods Sold

Cost of goods sold amounted to SEK 4.3 million for the three months ended September 30, 2022, and for the nine months ended September 30, 2022, cost of goods sold amounted to SEK 7.3 million. For the three and nine months ended September 30, 2021, no cost of goods sold were recognized.

## Total Operating Expenses

Total operating expenses amounted to SEK 292.0 million and SEK 190.3 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, total operating expenses amounted to SEK 821.0 million and SEK 500.5 million, respectively.

## Research and Development Expenses

Research and development expenses amounted to SEK 102.9 million and SEK 92.1 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, research and development expenses amounted to SEK 312.5 million and SEK 257.2 million, respectively. The increase of SEK 10.8 million for the three months ended September 30, 2022, and SEK 55.3 million for the nine months ended September 30, 2022, was primarily due to the setanaxib trials and the development of setanaxib compared to the corresponding periods of the prior year.

## Marketing and Selling Expenses

Marketing and selling expenses amounted to SEK 116.1 million and SEK 31.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, marketing and selling expenses amounted to SEK 323.3 million and SEK 109.0 million, respectively. The increase of SEK 84.9 million for the three months ended September 30, 2022, and SEK 214.3 million for the nine months ended September 30, 2022, was primarily related to the costs for sales and marketing of TARPEYO in the U.S., including the costs for the sales force compared to the corresponding periods of the prior year.

## Administrative Expenses

Administrative expenses amounted to SEK 71.0 million and SEK 64.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, administrative expenses amounted to SEK 178.4 million and SEK 129.6 million, respectively. The increase of SEK 6.8 million for the three months ended September 30, 2022, and SEK 48.8 million for the nine months ended September 30, 2022, was primarily related to general cost increases due to a larger organization and increased regulatory requirements compared to the corresponding periods of the prior year.

## Other Operating Incomes/Expenses, net

Other operating income/(expenses), net amounted to (SEK 1.9 million) and (SEK 2.8 million) for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, other operating income/(expenses), net amounted to (SEK 6.7 million) and (SEK 4.8 million), respectively. The increase for the nine months ended September 30, 2022, was primarily related to a more disadvantageous exchange rate development on operating liabilities compared to the corresponding period of the prior year.

## Net Financial Income and Expenses

Net financial income/(expenses) amounted to SEK 20.3 million and (SEK 1.4 million) for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, net financial income amounted to SEK 35.0 million and SEK 7.4 million, respectively. The increase of SEK 21.7 million for the three months ended September 30, 2022 and SEK 27.6 million for the nine months ended September 30, 2022 was primarily derived by currency effect related to intercompany loan and unrealized foreign currency transaction gains on cash accounts.

## FINANCIAL OVERVIEW

### Tax

Total income tax/(expense) amounted to SEK 6.8 million and (SEK 0.3 million) for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, income tax amounted to SEK 10.9 million and SEK 4.0 million, respectively. The increase for the three and nine months ended September 30, 2022 were primarily explained by recognized loss carried-forward, which are expected to be utilized against future profit for the U.S. subsidiaries. The group has also recognized losses carried-forward related to the Swiss subsidiary, which there are temporary differences that such taxable losses can be used to offset. The Group's tax losses carried-forward have otherwise not been recognized as deferred tax assets.

### Result for the Period

For the three months ended September 30, 2022 and 2021, loss for the period amounted to SEK 9.1 million and SEK 6.2 million, and the corresponding earnings/(loss) per share before and after dilution amounted to (SEK 0.17) and SEK 0.21, respectively. For the nine months ended September 30, 2022 and 2021, loss for the period amounted to SEK 408.6 million and SEK 290.9 million, and the corresponding loss per share before and after dilution amounted to SEK 7.72 and SEK 5.53, respectively.

### Cash Flow and Cash Position

Cash flow used in operating activities amounted to SEK 124.7 million and SEK 33.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, cash flow used in operating activities amounted to SEK 541.4 million and SEK 300.3 million, respectively. The increase in cash flow used in operating activities for the three and nine months ended September 30, 2022, were primarily explained by the increase in sales and marketing expenses for the TARPEYO sales in the U.S. and the Group's increased clinical activities for setanaxib compared to the corresponding periods of the prior year.

Cash flow used in investing activities amounted to SEK 0.9 million and SEK 0.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, cash flow used in investing activities amounted to SEK 3.7 million and SEK 19.0 million, respectively. The decrease in cash flow used in investing activities for the nine months ended September 30, 2022 were mainly derived from a EUR 1.5 million milestone payment for the Budenofalk license, which occurred the corresponding periods of the prior year.

Cash flow from/(used in) financing activities amounted to (SEK 2.6 million) and SEK 486.8 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, cash flow from financing activities amounted to SEK 293.4 million and SEK 476.5 million, respectively. The decrease in cash flow from financing activities for the three and nine months ended September 30, 2022, compared to the corresponding periods of the prior year, was primarily due to a new share issue of net SEK 304.0 million in the third quarter of 2021.

Net increase/(decrease) in cash amounted to (SEK 128.2 million) and SEK 453.3 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, net increase/(decrease) in cash amounted to (SEK 251.7 million) and SEK 157.1 million, respectively. Cash amounted to SEK 736.2 million and SEK 1,163.8 million as of September 30, 2022 and 2021, respectively.

### Changes in Shareholders' Equity and Number of Shares

Equity attributable to equity holders of the Parent Company amounted to SEK 725.9 million and SEK 1,255.0 million as of September 30, 2022 and 2021, respectively. The number of registered shares amounted to 59,157,587 and 52,341,584 as of September 30, 2022 and 2021, respectively. The increase in number of shares between the periods was derived from a new share issue in April and May 2022 of 856,586 shares related to the Warrant Program 2018/2022, a new share issue of 51,399 shares related to the Board LTIP 2019 program and a new issue of 5,908,018 shares held as treasury shares for future potential delivery of shares under the company's at-the-market program.

### Issuance and Repurchase of Treasury Shares

For the nine months ended September 30, 2022, Calliditas resolved to carry out an issue of 5,908,018 C-shares at a subscription price of SEK 0.04 per share and to subsequently immediately repurchased the 5,908,018 newly issued C-shares for SEK 0.04 per share and subsequently was converted into ordinary shares in accordance with the company's articles of association and held as treasury shares. The purpose of the issue and repurchase is to secure future potential delivery of shares under the company's at-the-market program. The share issue has increased the share capital by SEK 0.2 million. See Note 10 for additional information.

### Personnel

The number of employees were 98 and 65 employees as of September 30, 2022 and 2021, respectively. The total number of full-time equivalent (FTE), including consultants, were 169 and 81 as of September 30, 2022 and 2021, respectively. The average number of employees were 92 and 62 employees for the three months ended September 30, 2022 and 2021, respectively and 81 and 51 employees for the nine months ended September 30, 2022 and 2021, respectively.

### Incentive Programs

For the three months ended September 30, 2022, an allocation of 1,101,000 options have been granted for the ESOP 2022 program. For more information on incentive programs, see Note 11.

## FINANCIAL OVERVIEW

### 2022 Outlook

In 2021, the FDA granted accelerated approval for TARPEYO in the U.S. During the beginning of 2022, commercialization began in the U.S. and as a result, Calliditas expects accelerated revenue growth in the U.S. market and:

Net sales from TARPEYO from the U.S. are estimated to be USD 35-40 million for the year ending December 31, 2022, (corresponding to approx. 347-397 MSEK, using Riksbanken SEK/USD average exchange rate for the period January-September 2022 of 9.92).

### Parent Company

Net sales for the Parent Company, Calliditas Therapeutics AB, amounted to SEK 219.6 million and SEK 198.2 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, net sales amounted to SEK 251.8 million and SEK 198.2 million, respectively. The increase for the three and nine months ended September 30, 2022 was primarily derived from sales of TARPEYO compared to the corresponding periods of the prior year. Operating profit/(loss) amounted to (SEK 47.4 million) and SEK 49.8 million for the three months ended September 30, 2022 and 2021, respectively. For the nine months ended September 30, 2022 and 2021, operating loss amounted to SEK 302.1 million and SEK 201.8 million, respectively. The decrease for both periods was primarily derived from larger organization compared to the corresponding periods of the prior year. Non-current financial assets have increased by SEK 247.8 million to SEK 800.7 million as of September 30, 2022, compared to December 31, 2021, which was primarily derived from intercompany transactions.

Stockholm, November 14, 2022

Renée Aguiar-Lucander  
CEO

# Review report

## Calliditas Therapeutics AB, corporate identity number 556659-9766

### Introduction

We have reviewed the condensed interim report for Calliditas Therapeutics AB as at September 30, 2022 and for the nine months period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of review

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 Review of Interim Financial Statements Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

Stockholm 14 November 2022

Ernst & Young AB

Anna Svanberg  
Authorized Public Accountant

## FINANCIAL STATEMENTS

### Condensed Consolidated Statements of Income

(SEK in thousands, except per share amounts)	Notes	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
		2022	2021	2022	2021	2021
Net sales	4	260,056	198,167	373,837	198,167	229,347
Cost of goods sold		(4,322)	-	(7,322)	-	-
<b>Gross profit</b>		<b>255,734</b>	<b>198,167</b>	<b>366,515</b>	<b>198,167</b>	<b>229,347</b>
Research and development expenses		(102,877)	(92,098)	(312,510)	(257,194)	(357,485)
Marketing and selling expenses	13	(116,135)	(31,171)	(323,303)	(108,965)	(179,603)
Administrative expenses	13	(71,003)	(64,200)	(178,441)	(129,558)	(210,630)
Other operating income		1,065	2,153	2,166	2,536	259
Other operating expenses		(3,011)	(4,994)	(8,864)	(7,309)	(6,344)
<b>Operating profit/(loss)</b>		<b>(36,227)</b>	<b>7,856</b>	<b>(454,438)</b>	<b>(302,323)</b>	<b>(524,456)</b>
Net financial income/(expenses)		20,269	(1,375)	34,955	7,417	11,083
<b>Profit/(loss) before income tax</b>		<b>(15,958)</b>	<b>6,480</b>	<b>(419,483)</b>	<b>(294,906)</b>	<b>(513,373)</b>
Income tax		6,848	(321)	10,896	4,035	3,836
<b>Profit/(loss) for the period</b>		<b>(9,111)</b>	<b>6,159</b>	<b>(408,587)</b>	<b>(290,871)</b>	<b>(509,537)</b>
Attributable to:						
Equity holders of the Parent Company		(9,111)	10,573	(408,587)	(281,123)	(500,293)
Non-controlling interests		-	(4,414)	-	(9,748)	(9,244)
		<b>(9,111)</b>	<b>6,159</b>	<b>(408,587)</b>	<b>(290,871)</b>	<b>(509,537)</b>
Earnings/(loss) per share before dilution (SEK)		(0.17)	0.21	(7.72)	(5.53)	(9.84)
Earnings/(loss) per share after dilution (SEK)		(0.17)	0.21	(7.72)	(5.53)	(9.84)



## FINANCIAL STATEMENTS

### Condensed Consolidated Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Profit/(loss) for the period	(9,111)	6,159	(408,587)	(290,871)	(509,537)
<b>Other comprehensive income</b>					
<i>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:</i>					
Exchange differences on translation of foreign operations	4,558	2,639	34,626	4,919	(20,111)
<b>Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods</b>	<b>4,558</b>	<b>2,639</b>	<b>34,626</b>	<b>4,919</b>	<b>(20,111)</b>
<i>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:</i>					
Remeasurement gain on defined benefit plans	(94)	236	2,377	1,761	1,993
<b>Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods</b>	<b>(94)</b>	<b>236</b>	<b>2,377</b>	<b>1,761</b>	<b>1,993</b>
<b>Other comprehensive income/(loss) for the period</b>	<b>4,464</b>	<b>2,875</b>	<b>37,003</b>	<b>6,680</b>	<b>(18,118)</b>
<b>Total comprehensive income/(loss) for the period</b>	<b>(4,647)</b>	<b>9,034</b>	<b>(371,584)</b>	<b>(284,191)</b>	<b>(527,655)</b>
Attributable to:					
Equity holders of the Parent Company	(4,647)	13,113	(371,584)	(275,219)	(519,190)
Non-controlling interests	-	(4,079)	-	(8,973)	(8,466)
	<b>(4,647)</b>	<b>9,034</b>	<b>(371,584)</b>	<b>(284,191)</b>	<b>(527,655)</b>

## FINANCIAL STATEMENTS

### Condensed Consolidated Statements of Financial Position

(SEK in thousands)	Notes	September 30,		December 31,
		2022	2021	2021
<b>ASSETS</b>				
<b>Non-current assets</b>				
Intangible assets	6,13	487,348	441,451	399,418
Equipment		7,700	1,190	6,309
Right-of-use assets		28,161	20,086	33,300
Non-current financial assets		6,909	3,944	3,915
Deferred tax assets		14,889	2,600	4,196
<b>Total non-current assets</b>		<b>545,007</b>	<b>469,271</b>	<b>447,138</b>
<b>Current assets</b>				
Inventories		582	-	889
Accounts receivable		176,832	-	-
Other current receivables		10,347	55,474	11,343
Prepaid expenses and accrued income		49,175	36,867	45,032
Cash		736,161	1,163,818	955,507
<b>Total current assets</b>		<b>973,099</b>	<b>1,256,159</b>	<b>1,012,772</b>
<b>TOTAL ASSETS</b>		<b>1,518,106</b>	<b>1,725,430</b>	<b>1,459,910</b>
<b>EQUITY AND LIABILITIES</b>				
<b>Equity</b>				
Share capital		2,366	2,094	2,094
Additional paid-in-capital		2,548,946	2,451,979	2,459,741
Retained earnings, including net loss for the period		(1,825,376)	(1,199,026)	(1,453,554)
<b>Equity attributable to equity holders of the Parent Company</b>		<b>725,936</b>	<b>1,255,047</b>	<b>1,008,281</b>
Non-controlling interests		-	27,957	-
<b>Total equity</b>	9,10,11	<b>725,936</b>	<b>1,283,004</b>	<b>1,008,281</b>
<b>Non-current liabilities</b>				
Provisions	11	8,030	14,201	17,712
Contingent consideration		62,365	52,973	54,399
Deferred tax liabilities	7,13	34,338	33,312	30,856
Non-current interest-bearing liabilities	12	448,129	187,427	189,164
Lease liabilities		19,188	14,441	24,052
<b>Total non-current liabilities</b>		<b>572,049</b>	<b>302,354</b>	<b>316,183</b>
<b>Current liabilities</b>				
Accounts payable		95,763	74,855	67,971
Other current liabilities		14,796	10,642	13,922
Accrued expenses and deferred revenue		109,561	54,574	53,553
<b>Total current liabilities</b>		<b>220,120</b>	<b>140,072</b>	<b>135,446</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>1,518,106</b>	<b>1,725,430</b>	<b>1,459,910</b>

## FINANCIAL STATEMENTS

### Condensed Consolidated Statements of Changes in Equity

(SEK in thousands)	Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2021
<b>Opening balance equity attributable to equity holders of the Parent Company</b>	<b>1,008,281</b>	<b>1,210,491</b>	<b>1,210,491</b>
Loss for the period	(408,587)	(281,123)	(500,293)
Other comprehensive income/(loss)	37,003	5,905	(18,897)
<b>Total comprehensive income/(loss) for the period attributable to equity holders of the Parent Company</b>	<b>(371,584)</b>	<b>(275,219)</b>	<b>(519,190)</b>
<b>Transactions with owners:</b>			
New share issue	-	324,000	324,000
Costs attributable to new share issue	-	(20,909)	(20,909)
Issuance of treasury shares	236	-	-
Repurchase of treasury shares	(236)	-	-
Exercise of warrants	63,644	-	-
Share-based payments	25,595	15,805	23,567
Purchase of non-controlling interests	-	879	(9,678)
<b>Total transactions with owners</b>	<b>89,239</b>	<b>319,775</b>	<b>316,980</b>
<b>Closing balance equity attributable to equity holders of the Parent Company</b>	<b>725,936</b>	<b>1,255,047</b>	<b>1,008,281</b>
<b>Opening balance equity attributable to non-controlling interests</b>	<b>-</b>	<b>45,809</b>	<b>45,809</b>
Total comprehensive loss for the period	-	(8,973)	(8,466)
Contribution from non-controlling interests	-	2,282	2,282
Purchase of non-controlling interests	-	(11,162)	(39,625)
<b>Closing balance equity attributable to non-controlling interests</b>	<b>-</b>	<b>27,957</b>	<b>-</b>
<b>Closing balance equity</b>	<b>725,936</b>	<b>1,283,004</b>	<b>1,008,281</b>

## FINANCIAL STATEMENTS

### Condensed Consolidated Statements of Cash Flows

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
<b>Operating activities</b>					
Operating profit/(loss)	(36,227)	7,856	(454,438)	(302,323)	(524,456)
Adjustment for non-cash-items	11,173	8,912	30,344	24,136	66,676
Interest received	-	-	2	-	102
Interest paid	(12,830)	(327)	(23,676)	(536)	(5,432)
Income taxes paid	(1,788)	(477)	(4,718)	(1,470)	(3,949)
<b>Cash flow used in operating activities before changes in working capital</b>	<b>(39,672)</b>	<b>15,963</b>	<b>(452,485)</b>	<b>(280,193)</b>	<b>(467,058)</b>
Cash flow from/(used in) changes in working capital	(85,053)	(49,208)	(88,898)	(20,141)	5,470
<b>Cash flow used in operating activities</b>	<b>(124,725)</b>	<b>(33,245)</b>	<b>(541,383)</b>	<b>(300,334)</b>	<b>(461,588)</b>
Cash flow used in investing activities	(888)	(236)	(3,678)	(19,003)	(24,340)
<b>Cash flow used in investing activities</b>	<b>(888)</b>	<b>(236)</b>	<b>(3,678)</b>	<b>(19,003)</b>	<b>(24,340)</b>
New share issue	-	324,000	-	324,000	324,000
Costs attributable to new share issue	-	(19,927)	-	(20,909)	(20,909)
Issuance of treasury shares	-	-	236	-	-
Repurchase of treasury shares	-	-	(236)	-	-
Exercise of warrants	-	-	63,644	-	-
Purchase of non-controlling interests	-	-	-	(10,283)	(49,303)
Contribution from non-controlling interests	-	-	-	2,282	2,282
New borrowings	-	199,524	236,462	199,524	199,524
Costs attributable to new loans	-	(14,857)	-	(14,857)	(14,857)
Repayment of lease liabilities	(2,569)	(1,944)	(6,754)	(3,305)	(5,575)
<b>Cash flow from/(used in) financing activities</b>	<b>(2,569)</b>	<b>486,795</b>	<b>293,353</b>	<b>476,451</b>	<b>435,162</b>
<b>Net increase/(decrease) in cash</b>	<b>(128,183)</b>	<b>453,315</b>	<b>(251,708)</b>	<b>157,115</b>	<b>(50,766)</b>
<b>Cash at the beginning of the period</b>	<b>846,799</b>	<b>709,306</b>	<b>955,507</b>	<b>996,304</b>	<b>996,304</b>
Net foreign exchange gains/(loss) on cash	17,545	1,198	32,362	10,400	9,969
<b>Cash at the end of the period</b>	<b>736,161</b>	<b>1,163,818</b>	<b>736,161</b>	<b>1,163,818</b>	<b>955,507</b>

## FINANCIAL STATEMENTS

### Condensed Parent Company Statements of Income

(SEK in thousands)	Notes	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
		2022	2021	2022	2021	2021
Net sales	4	219,642	198,167	251,833	198,167	229,347
Cost of goods sold		(4,322)	-	(7,322)	-	-
<b>Gross profit</b>		<b>215,320</b>	<b>198,167</b>	<b>244,511</b>	<b>198,167</b>	<b>229,347</b>
Research and development expenses		(94,340)	(79,258)	(286,729)	(210,631)	(275,950)
Marketing and selling expenses		(134,066)	(23,539)	(196,873)	(92,110)	(151,125)
Administrative expenses		(57,378)	(68,217)	(151,720)	(134,027)	(226,349)
Other operating income		24,650	26,362	93,462	41,035	70,234
Other operating expenses		(1,564)	(3,746)	(4,712)	(4,199)	(1,874)
<b>Operating profit/(loss)</b>		<b>(47,377)</b>	<b>49,769</b>	<b>(302,061)</b>	<b>(201,766)</b>	<b>(355,718)</b>
Net financial income/(expenses)		7,500	(865)	13,341	8,441	1,312
<b>Profit/(loss) before income tax</b>		<b>(39,877)</b>	<b>48,903</b>	<b>(288,720)</b>	<b>(193,326)</b>	<b>(354,405)</b>
Income tax		-	-	-	-	-
<b>Profit/(loss) for the period</b>		<b>(39,877)</b>	<b>48,903</b>	<b>(288,720)</b>	<b>(193,326)</b>	<b>(354,405)</b>

### Condensed Parent Company Statements of Comprehensive Income

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
Profit/(loss) for the period	(39,877)	48,903	(288,720)	(193,326)	(354,405)
Other comprehensive income/(loss)	-	-	-	-	-
<b>Total comprehensive income/(loss)</b>	<b>(39,877)</b>	<b>48,903</b>	<b>(288,720)</b>	<b>(193,326)</b>	<b>(354,405)</b>

## FINANCIAL STATEMENTS

### Condensed Parent Company Balance Sheet

(SEK in thousands)	Notes	September 30,		December 31,
		2022	2021	2021
<b>ASSETS</b>				
<b>Non-current assets</b>				
Intangible assets	6	32,132	32,132	32,132
Equipment		623	-	514
Non-current financial assets		800,703	399,515	552,924
<b>Total non-current assets</b>		<b>833,457</b>	<b>431,646</b>	<b>585,570</b>
<b>Current assets</b>				
Inventories		582	-	889
Accounts receivable		111,288	-	-
Other current receivables		100,826	84,857	5,699
Prepaid expenses and accrued income		27,410	34,981	41,825
Cash		632,236	1,131,555	894,455
<b>Total current assets</b>		<b>872,342</b>	<b>1,251,392</b>	<b>942,868</b>
<b>TOTAL ASSETS</b>		<b>1,705,800</b>	<b>1,683,039</b>	<b>1,528,439</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>				
<b>Restricted Shareholders' equity</b>				
Share capital		2,366	2,094	2,094
Statutory reserve		3,092	3,092	3,092
<b>Total restricted Shareholders' equity</b>		<b>5,458</b>	<b>5,186</b>	<b>5,186</b>
<b>Non-restricted shareholders' equity</b>				
Share premium reserve		2,487,126	2,420,698	2,420,698
Retained earnings		(1,195,042)	(870,937)	(863,175)
Net loss for the period		(288,720)	(193,326)	(354,405)
<b>Total non-restricted shareholders' equity</b>		<b>1,003,365</b>	<b>1,356,435</b>	<b>1,203,117</b>
<b>Total shareholders' equity</b>	9,11	<b>1,008,823</b>	<b>1,361,621</b>	<b>1,208,303</b>
<b>Non-current liabilities</b>				
Provisions	11	4,209	5,024	9,075
Non-current interest-bearing liabilities	12	448,129	187,427	189,164
Other non-current liabilities		105	105	105
<b>Total non-current liabilities</b>		<b>452,443</b>	<b>192,557</b>	<b>198,344</b>
<b>Current liabilities</b>				
Accounts payable		44,217	70,382	51,711
Other current liabilities		139,699	21,374	33,466
Accrued expenses and deferred revenue		60,617	37,106	36,615
<b>Total current liabilities</b>		<b>244,534</b>	<b>128,861</b>	<b>121,792</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>1,705,800</b>	<b>1,683,039</b>	<b>1,528,439</b>

### Notes to Condensed Consolidated Financial Statements

#### Note 1 - Description of Business

Calliditas Therapeutics AB (publ) ("Calliditas" or the "Parent Company"), with corporate registration number 556659-9766, and its subsidiaries (collectively, the "Group") conducts commercial and development activities in pharmaceuticals. These interim condensed consolidated financial statements encompass the Group, domiciled in Stockholm, Sweden, and its subsidiaries for the nine months ended September 30, 2022 and 2021, respectively.

Calliditas is a Swedish public limited company registered in and with its registered office in Stockholm. The registered address of the corporate headquarters is Kungsbron 1, D5, Stockholm, Sweden. Calliditas is listed at Nasdaq Stockholm in the Mid Cap segment with ticker "CALTX" and, in the form of ADSs, on the Nasdaq Global Select Market in the United States with the ticker "CALT".

These interim condensed consolidated financial statements were approved by the Board of Directors (the "Board") for publication on November 14, 2022.

This report may include forward-looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, (e.g. the economic climate, political changes, and competing research projects) that may affect the Group's results.

#### Note 2 - Accounting Policies

These interim condensed consolidated financial statements have been prepared in accordance with International Accounting Standard No. 34 (IAS 34), "Interim Financial Reporting". The Parent Company applies the Swedish Financial Reporting Board recommendation RFR2, Accounting for legal entities. None of the new or amended standards and interpretations that became effective January 1, 2022, have had a significant impact on the Group's financial reporting. Significant accounting principles can be found on pages 41-46 of the Annual Report for 2021.

The ESMA (European Securities and Markets Authority) guidelines on alternative key performance ratios are applied, which means disclosure requirements regarding financial measures that are not defined in accordance with IFRS. For key ratios not defined by IFRS, see the Definitions and reconciliations of alternative performance measures on pages 31-32.

#### Note 3 - Risks and Uncertainties in the Group and the Parent Company Operational Risks

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risk such as the risk for insufficient efficacy, intolerable side effects or manufacturing problems. Competing pharmaceuticals can capture market share or reach the market faster, or if competing research projects achieve better product profiles, the future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as lack of approvals and price changes.

Calliditas has a product in the commercial phase, which is marketed under the brand name TARPEYO, which has been approved for marketing in the U.S under an accelerated approval, and under the brand name Kinpeygo, which has received conditional marketing authorization in EU and undermine renewal of the current conditional marketing authorisation. There is a risk that commercialization

will not go according to plan or that the uptake of prescribing physicians will be worse than planned or that the drug will not have sufficient effect or show unwanted side effects, which may affect the sales negatively.

#### COVID-19

The COVID-19 virus has rapidly spread from an initial event and infections have been reported globally. Calliditas has clinical trial sites based in areas currently affected by this coronavirus. Calliditas has not yet experienced any major disturbances in the trials. The extent to which the coronavirus impacts the operations and the trials, or any planned trials for Nefecon or setanaxib, will depend on the type, degree and duration of the various restrictions put in place to contain the virus or treat those affected. This today varies in different geographies, and future developments cannot be predicted with reasonable assurance.

The pandemic may negatively impact our trials as a result of disruptions, such as travel bans, quarantines, and inability of patients to access the trial sites and provide samples as well as interruptions in the supply chain, which could result in delays and impact on the data integrity of the trials. The impact of the coronavirus outbreak for Calliditas have been limited so far, but the continued spread of the coronavirus globally, may negatively impact our operations, including our trials. It could also negatively affect the operations of key governmental agencies, such as the FDA and EMA, which may delay the development of our product candidates, or could result in the inability of our suppliers to deliver components or raw materials on a timely basis, each of which in turn could have a negative impact on our business and results of operations.



### Financial Risks

Calliditas' financial policy governing the management of financial risks has been designed by the Board of Directors and represents the framework of guidelines and rules in the form of risk mandated and limits for financial activities. The Group is primarily affected by foreign exchange risk, since the development costs for Nefecon and setanaxib are mainly paid in USD and EUR. Further, the Group holds accounts receivables in USD and cash in USD and EUR to meet future expected costs in USD and EUR in connection with commercialization of TARPEYO in the U.S. and the clinical development programs. Regarding the Group and the Parent Company's financial risk management, the risks are essentially unchanged compared with the description in the Annual Report for 2021.

For more information and full disclosure regarding the operational and financial risks, reference is made to the Annual Report for 2021 and the Annual Report on Form 20-F, filed with the SEC in April 2022.

### Note 4 - Revenue from Contracts with Customers

(SEK in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
<b>Type of goods or services</b>					
Product sales	125,045	-	206,634	-	-
Outlicensing of product	135,012	198,167	163,816	198,167	225,252
Performance of certain regulatory services	-	-	3,387	-	4,095
<b>Total</b>	<b>260,056</b>	<b>198,167</b>	<b>373,837</b>	<b>198,167</b>	<b>229,347</b>
<b>Geographical markets</b>					
USA	123,400	-	204,989	-	-
Europe	136,656	198,167	140,044	198,167	201,878
Asia	-	-	28,804	-	27,469
<b>Total</b>	<b>260,056</b>	<b>198,167</b>	<b>373,837</b>	<b>198,167</b>	<b>229,347</b>

The Group's revenues for the three and nine months ended September 30, 2022 primarily originates from net sales of TARPEYO in the U.S. and milestone fees from STADA for the conditional approval and commercialization in Europe. Further for the nine months ended September 30, 2022, net sales also consisted of the milestone fee from Everest Medicines for the extension of the license agreement for South Korea.

Revenue from product sales is recognized at the transaction price of goods sold excluding VAT, rebates and returns. At the time of delivery, when the control of the goods passes to the customer, the revenue is recognized in full, as this represents the single performance obligation in the transaction. The customer is defined as the specialty pharmaceutical who dispenses the good to the end user. As the final price is related to the rebate paid to the patients' insurance company, the transaction price is not known upon delivery. This is accounted for by an accrued estimated rebate deduction in the Group based on calculation models considering statistical data, actual amounts incurred and/or historical trends. These liabilities for expected returns and rebates are based on estimates of the amounts earned or to be claimed on the related sales. Furthermore, the Group estimates the liability for expected returns of obsolete medicines that is recognized in the accounts. As of September 30, 2022 the total liability for expected returns and rebates amounts to SEK 17.2 million. In addition, there are no other performance obligations.

Revenue attributable to out-licensing Nefecon consisted of the agreement with STADA for Europe and the expansion of Everest Medicines to South Korea. Revenue for out-licensing is recognized at a point in time, which occurs when control over the intangible asset is transferred to the counterparty, which was at the time when the agreements with both parties was signed. Variable remuneration (for example, attributable to future regulatory milestones) is recognized when there is no longer any significant uncertainty as to whether these will occur. Compensation attributable to sales-based milestones or royalties are not recognized until the sale that results in the right to milestones or royalties arises.

Calliditas has identified three performance obligations under the agreement with STADA: 1) Out-licensing of the product candidate Nefecon as is at the time of signing, 2) Contractual obligation to perform the regulatory process with the EMA to obtain Conditional Regulatory Approval and 3) The obligation to supply Nefecon. Calliditas has completed all the performance obligations within the agreement with STADA and Everest Medicines, except the supply of Nefecon which will be performed against order.

### Note 5 - Related-Party Transactions

During the reporting period, no significant related-party transactions have occurred. For information about incentive programs please see Note 11.

### Note 6 - Intangible Assets

(SEK in thousands)	September 30,		December 31,
	2022	2021	2021
Cost at opening balance	427,393	418,825	418,825
Acquisition license	-	16,066	16,066
Exchange difference on translation	87,930	6,560	(7,498)
<b>Cost at closing balance</b>	<b>515,323</b>	<b>441,451</b>	<b>427,393</b>
<b>Accumulated amortisation and impairment at closing balance</b>	<b>(27,975)</b>	<b>-</b>	<b>(27,975)</b>
<b>Net book value</b>	<b>487,348</b>	<b>441,451</b>	<b>399,418</b>

Intangible assets consist of licenses and similar rights of SEK 441.2 million and goodwill of SEK 46.1 million as of September 30, 2022. As of September 30, 2021, intangible assets consist of licenses and similar rights of SEK 402.8 million and goodwill of SEK 38.6 million.

### Note 7 - Deferred Tax Liabilities

(SEK in thousands)	September 30,		December 31,
	2022	2021	2021
Cost at opening balance	30,857	37,454	37,454
Tax loss carried forward	(5,519)	(4,835)	(5,065)
Exchange difference on translation	9,000	693	(1,532)
<b>Cost at closing balance</b>	<b>34,338</b>	<b>33,312</b>	<b>30,857</b>

Tax loss carried forward of SEK 22.9 million have been offset against deferred tax liabilities in the statement of financial position as of September 30, 2022 due to future temporary differences that such losses can be used to offset.

### Note 8 - Financial Instruments

The Group's financial assets comprise of non-current financial assets, accounts receivables and cash, which are recognized at amortized cost. The Group's financial liabilities comprise of contingent consideration, non-current interest-bearing liabilities, lease liabilities, accounts payable and other current liabilities, all of which except contingent consideration, are recognized at amortized cost. The carrying amount is an approximation of the fair value. Contingent considerations are recognized at fair value, measured at Level 3 of the IFRS value hierarchy.

## Note 9 - Shareholders' Equity

(SEK in thousands, except per share amounts and number of shares)	September 30,		December 31,		
	2022	2021	2021		
Total registered shares at the beginning of the period	52,341,584	49,941,584	49,941,584		
New issue of shares during the period	6,816,003	2,400,000	2,400,000		
<b>Total registered shares at the end of the period</b>	<b>59,157,587</b>	<b>52,341,584</b>	<b>52,341,584</b>		
<b>Shares</b>					
Ordinary shares	59,157,587	52,341,584	52,341,584		
<b>Total</b>	<b>59,157,587</b>	<b>52,341,584</b>	<b>52,341,584</b>		
- of which shares are held by Calliditas	5,908,018	-	-		
<b>Total registered shares at the end of the period, net of shares held by Calliditas</b>	<b>53,249,569</b>	<b>52,341,584</b>	<b>52,341,584</b>		
Share capital at the end of the period	2,366	2,094	2,094		
Equity attributable to equity holders of the Parent Company	725,936	1,255,047	1,008,281		
Non-controlling interests	-	27,957	-		
<b>Equity at the end of the period</b>	<b>725,936</b>	<b>1,283,004</b>	<b>1,008,281</b>		
	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
(SEK in thousands, except per share amounts and number of shares)	2022	2021	2022	2021	2021
Earnings/(loss) per share before dilution, SEK	(0.17)	0.21	(7.72)	(5.53)	(9.84)
Earnings/(loss) per share after dilution, SEK	(0.17)	0.21	(7.72)	(5.53)	(9.84)
Weighted-average number of ordinary shares outstanding for the period, before dilution	53,247,334	51,063,323	52,942,807	50,829,255	50,829,255
Weighted-average number of ordinary shares outstanding for the period, after dilution	53,247,334	51,561,201	52,942,807	50,829,255	50,829,255

Reserves for translation from foreign operations amounted to SEK 7.6 million and (SEK 1.9 million) which are included in retained earnings in equity as of September 30, 2022 and 2021, respectively.

### Note 10 - Transactions in Treasury Shares

Since 2020, Calliditas has had ordinary shares, in the form of American Depositary Shares ("ADSs"), listed in the United States on The Nasdaq Global Select Market. Calliditas has now implemented and launched an At-The-Market program ("ATM Program"). The purpose of the ATM Program is to efficiently and cost-effectively raise capital, if necessary, in the U.S. market and to ensure delivery of shares to be sold under the company's ATM Program.

For the nine months ended September 30, 2022, 5,908,018 series C shares were issued, which were repurchased and converted to ordinary shares by Calliditas. These transactions are in accordance with the granting mandate. The total number of issued shares as of September 30, 2022, is presented in Note 9.

## Note 11 - Incentive Programs

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of September 30, 2022
<b>Incentive Programs</b>				
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2020	-	-	31,371	31,371
Board LTIP 2021	-	-	26,968	26,968
Board LTIP 2022	-	-	40,706	40,706
ESOP 2020	-	1,371,666	-	1,371,666
ESOP 2021	-	1,490,000	-	1,490,000
ESOP 2022	-	1,101,000	-	1,101,000
<b>Total Outstanding as of September 30, 2022</b>	<b>422,500</b>	<b>3,962,666</b>	<b>99,045</b>	<b>4,484,211</b>

	Warrants Outstanding	Options Outstanding	Share Awards Outstanding	Total Outstanding as of September 30, 2021
<b>Incentive Programs</b>				
Warrant program 2018/2022	856,586	-	-	856,586
Warrant program 2019/2022	422,500	-	-	422,500
Board LTIP 2019	-	-	51,399	51,399
Board LTIP 2020	-	-	31,371	31,371
Board LTIP 2021	-	-	26,968	26,968
ESOP 2020	-	1,455,000	-	1,455,000
ESOP 2021	-	850,000	-	850,000
<b>Total Outstanding as of September 30, 2021</b>	<b>1,279,086</b>	<b>2,305,000</b>	<b>109,738</b>	<b>3,693,824</b>

**Warrant Program 2019/2022:**

The warrants in the Warrant Program 2019/2022 can be exercised between October 1, 2022 and December 31, 2022, where each warrant gives the participant the right to subscribe for a new share in the Parent Company at a subscription price of SEK 74.50 per share. The warrants have, at the time of issue, been valued according to the Black & Scholes valuation model.

**Board LTIP 2020:**

This is a performance-based long-term incentive program for Calliditas Board members. A total of 31,371 share awards were granted under the program during the second quarter of 2020. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2020 Annual General Meeting to July 1, 2023.

**Board LTIP 2021:**

This is a performance-based long-term incentive program for Calliditas Board members. A total of 26,968 share awards were granted under the program during the second quarter of 2021. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2021 Annual General Meeting to July 1, 2024.

**Board LTIP 2022:**

This is a performance-based long-term incentive program for Calliditas Board members. A total of 40,706 share awards were granted under the program during the second quarter of 2022. The share awards are subject to performance-based earnings, which is dependent on the development of Calliditas' share price from the date of the 2022 Annual General Meeting to July 1, 2025.

**ESOP Programs**

Calliditas implements option programs for employees and key consultants in Calliditas. The options are allotted free of charge to participants of the program. The options have a three-year vesting period calculated from the allotment date, provided that, with customary exceptions, the participants remain as employees of, or continue to provide services to, Calliditas. Once the options are vested, they can be exercised within a one-year period. Each vested option entitles the holder to acquire one share in Calliditas at a predetermined price. The price per share is to be equivalent to 115% of the weighted average price that the company's shares were traded for on Nasdaq Stockholm during the ten trading days preceding the allotment date. The options have, at the time of each issue, been valued according to the Black & Scholes valuation model.

**Note 12 - Non-current interest-bearing liabilities**

(SEK in thousands)	September 30,		December 31,
	2022	2021	2021
Opening balance	189,164	-	-
New borrowings	236,584	199,524	199,524
Transaction costs	-	(14,858)	(14,858)
Interest expense	3,633	949	2,145
Exchange difference on translation	18,748	1,812	2,353
<b>Closing balance</b>	<b>448,129</b>	<b>187,427</b>	<b>189,164</b>

In July 2021, Calliditas signed a loan agreement of up to the euro equivalent of USD 75 million with Kreos Capital. The loan facility is divided into three tranches of USD 25 million each. Draw down of the first USD 25 million tranche was made in 2021. Draw down of the second tranche of USD 25 million was made in June, 2022. Draw down of the third and final USD 25 million tranche can be made until December 31, 2022, and will be available subject to certain coverage metrics. The interest rate on the loan is 9% per annum with a maturity to December 2025, which is recognized at Net financial income/(expenses). The loan has no financial covenants.

**Note 13 - Change of presentation of expenses and IFRS 3 adjustment****Change of Presentation of Expenses**

From January 1, 2022, Calliditas has switched to presenting marketing and selling expenses separately from administrative expenses. The purpose of the change is to provide more relevant information about the Group's and the Parent Company's financial results, and follow the practice in the industry for a company in commercial stage. The change constitutes a voluntary change and is applied with full retroactivity.

**Update of Purchase Price Allocation**

The fair value of the acquired assets and assessed liabilities for the acquisition of Calliditas Therapeutics Suisse S.A in 2020 was preliminarily established for the first 12 months and was thereafter finalized in 2021. The fair value of the acquisitions of Calliditas Therapeutics Suisse S.A changed due to allocation of assets and liabilities to Switzerland and therefore IFRS adjustments were made to the acquisition values. The effects of the change in the statement of income for the preceding periods are shown below:

(SEK in thousands)	Nine Months Ended September 30,				Year Ended December 31,		
	2021	Adjustment	Re-classification	2021	2021	Re-classification	2021
Net sales	198,167	-	-	198,167	229,347	-	229,347
<i>Operating expenses</i>							
Research and development expenses	(257,194)	-	-	(257,194)	(357,485)	-	(357,485)
Marketing and selling expenses	-	-	(108,965)	(108,965)	-	(179,603)	(179,603)
Administrative expenses	(238,522)	-	108,965	(129,557)	(390,232)	179,603	(210,629)
Other operating income/expenses	(4,773)	-	-	(4,773)	(6,085)	-	(6,085)
<b>Operating loss</b>	<b>(302,323)</b>	<b>-</b>	<b>-</b>	<b>(302,323)</b>	<b>(524,456)</b>	<b>-</b>	<b>(524,456)</b>
Net financial income/(expenses)	7,417	-	-	7,417	11,083	-	11,083
<b>Loss before income tax</b>	<b>(294,906)</b>	<b>-</b>	<b>-</b>	<b>(294,906)</b>	<b>(513,373)</b>	<b>-</b>	<b>(513,373)</b>
Income tax	11,415	(7,380)	-	4,035	3,836	-	3,836
<b>Loss for the period</b>	<b>(283,491)</b>	<b>(7,380)</b>	<b>-</b>	<b>(290,871)</b>	<b>(509,537)</b>	<b>-</b>	<b>(509,537)</b>



## NOTES

The below table describes the adjustment for the nine months ended September 30, 2021, compared to what prior has been published for the same period, regarding the statements of financial position from the finalization of the fair value.

(SEK in thousands)	September 30,		2021
	2021	Adjustment	
<b>ASSETS</b>			
<b>Non-current assets</b>			
Other intangible assets	436,664	(33,821)	402,843
Goodwill	48,022	(9,414)	38,608
Other non-current assets	27,819	-	27,819
<b>Total non-current assets</b>	<b>512,505</b>	<b>(43,235)</b>	<b>469,271</b>
<b>Current assets</b>	<b>1,256,159</b>	<b>-</b>	<b>1,256,159</b>
<b>TOTAL ASSETS</b>	<b>1,768,664</b>	<b>(43,235)</b>	<b>1,725,430</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	2,094	-	2,094
Additional paid in capital	2,451,979	-	2,451,979
Retained earnings, including net loss for the period	(1,192,224)	(6,802)	(1,199,026)
<b>Equity attributable to equity holders of the Parent Company</b>	<b>1,261,849</b>	<b>(6,802)</b>	<b>1,255,047</b>
Non-controlling interests	28,677	(720)	27,957
<b>Total equity</b>	<b>1,290,526</b>	<b>(7,522)</b>	<b>1,283,004</b>
<b>Non-current liabilities</b>			
Deferred tax liabilities	69,025	(35,713)	33,312
Other non-current liabilities	269,042	-	269,042
<b>Total non-current liabilities</b>	<b>338,067</b>	<b>(35,713)</b>	<b>302,354</b>
<b>Current liabilities</b>	<b>140,072</b>	<b>-</b>	<b>140,072</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1,768,664</b>	<b>(43,235)</b>	<b>1,725,430</b>

## Definitions of Performance Measures and Reconciliations of Alternative Performance Measures

### Definitions of Performance Measures

Performance Measures	Definitions
Earnings/(loss) per share before and after dilution	Earnings/(loss) for the period divided by the average number of share before and after dilution. Diluted earnings per share is calculated by adjusting the weighted average number of common share outstanding to assume conversion of all dilutive potential common shares, which is in accordance with IAS 33 Earnings Per Share.
Share capital at the end of the period	Share capital at the end of respective period. The measure is extracted from the statements of financial position.
Total outstanding shares at the beginning of period	Total outstanding shares at the beginning of respective period.
Total outstanding shares at the end of period	Total outstanding shares at the end of respective period.
Average number of outstanding shares during the period	Average number of outstanding shares of respective period.
Equity at the end of the period	Equity at the end of respective period. The measure is extracted from the statements of financial position.
Cash at the end of the period	Cash at the end of respective period. The measure is extracted from the statements of financial position.

### Definitions of Alternative Performance Measures

Alternative Key Performance Indicator	Definitions	Reason for Inclusion
Research and development expenses/ Total operating expenses in %	Research and development expenses, divided by total operating expenses, which is the sum of research and development expenses, marketing and selling expenses, administrative expenses and other operating income and expenses.	The key performance indicator helps the reader of the interim financial statements to analyse the portion of the Group's expenses that are attributable to the Group's research and development activities.
Equity ratio at the end of the period in %	The ratio at the end of respective period is calculated by dividing total shareholders' equity by total assets.	The equity ratio measures the proportion of the total assets that are financed by shareholders.

## Reconciliations of Alternative Performance Measures

(SEK in thousands or otherwise indicated)	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2022	2021	2022	2021	2021
<b>Research and development expenses/Total operating expenses in %</b>					
Research and development expenses	(102,877)	(92,098)	(312,510)	(257,194)	(357,485)
Marketing and selling expenses	(116,135)	(31,171)	(323,303)	(108,965)	(179,603)
Administrative expenses	(71,003)	(64,200)	(178,441)	(129,558)	(210,630)
Other operating income/expenses	(1,946)	(2,842)	(6,699)	(4,773)	(6,085)
<b>Total operating expenses</b>	<b>(291,961)</b>	<b>(190,311)</b>	<b>(820,953)</b>	<b>(500,490)</b>	<b>(753,803)</b>
<b>Research and development expenses/Total operating expenses in %</b>	<b>35%</b>	<b>48%</b>	<b>38%</b>	<b>51%</b>	<b>47%</b>

(SEK in thousands or otherwise indicated)	September 30,		December 31,
	2022	2021	2021
<b>Equity ratio at the end of the period in %</b>			
Total shareholders' equity at the end of the period	725,936	1,255,047	1,008,281
Total assets at the end of the period	1,518,106	1,725,430	1,459,910
<b>Equity ratio at the end of the period in %</b>	<b>48%</b>	<b>73%</b>	<b>69%</b>

### Financial Calendar

Year-End Report for the period January 1 - December 31, 2022

February 23, 2023

#### Contact

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#### Forward Looking Statements

This interim report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, business plans, revenue and other financial projections, and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this interim report are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this interim report, including, without limitation, any related to Calliditas' business, operations, commercialization of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines for development and potential approvals, competition from other biopharmaceutical companies, revenue and product sales projections or forecasts, and other risks identified in the section entitled "Risk Factors" Calliditas' reports filed with the Securities and Exchange Commission.

Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this interim report represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

This report has been prepared in a Swedish original and has been translated into English. In case of differences between the two, the Swedish version shall apply.

