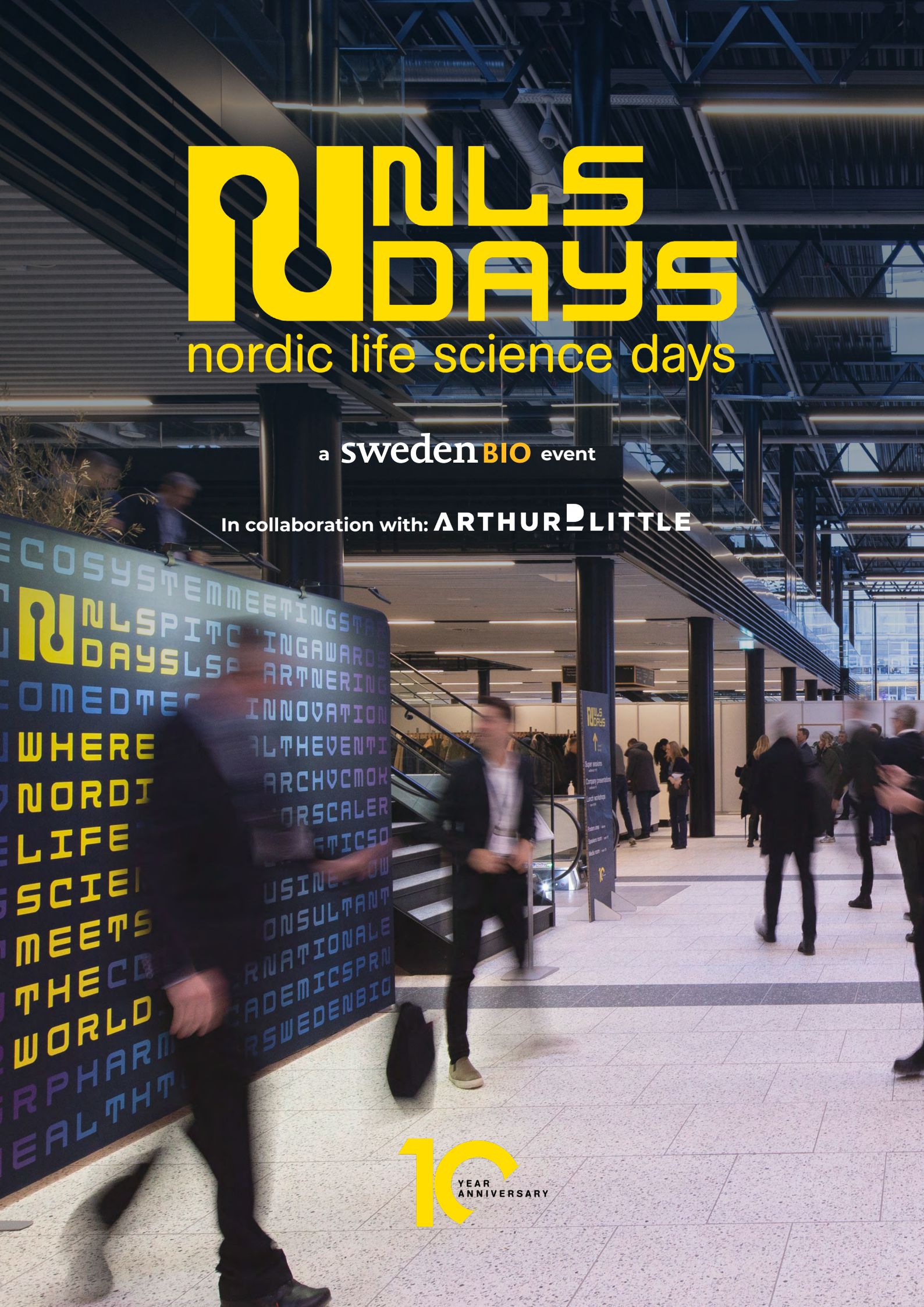
NLS DAYS
nordic life science days
a swedenBIO event
In collaboration with: ARTHUR D LITTLE
10 YEAR ANNIVERSARY

10th Year of NLSDays

In November 2023, the Nordic Life Science Days (NLSDays) celebrated its tenth annual gathering, attracting professionals and thought leaders from across the globe to delve into the latest advancements in the life sciences industry. This unique event from the industry for the industry has grown steadily over the past 10 years and is now attracting more than 1600 delegates, who took the opportunity ofimmersing themselves in topics around innovation and its translation into life sciences. For the first time since its inception the event took place outside of Sweden in a wintry Copenhagen. The attendees represented not only a diverse range of sectors, including pharmaceuticals, biotechnology, academics, medical devices, diagnostics, C(D)MOs, CROs, investors and professional services, but also countries and companies well beyond the Nordics. NLSDays 2023 had a record number of country pavilions hosted by Norway, Denmark, Sweden, Finland, Iceland, France, Germany, Flanders – Belgium, Alabama – USA, the Netherlands, and the United Kingdom.

> *"This event always feels like a class meeting – a great opportunity to reconnect with peers from the region.*
>
> *Participant, Biotech*

> *"You can really feel that this is an event from the industry by the industry and not another commercial event.*
>
> *Participant, Big Pharma*

As in previous NLSDays the three-day event centered around partnering and six supersessions with panel discussions on highly relevant and current topics such as "Preparing for the next unicorn: how to choose your business strategy", "Harnessing data to improve our health" or a closer look at "Opportunities and challenges with new drug modalities" and the newly emerging focus on the "New era in CNS: Rising from the ashes", which were very well attended and provided a diverse view on these topics. It was also a great opportunity to get an inside view on what is shaping innovation in the life sciences in the Nordics and beyond and what is top of mind for leaders and shapers across the industry. Surprisingly, the topic of AI, which has been dominating the media and many discussions throughout 2023, was a side topic within the larger questions of:

1. Where are we heading as an industry and what is the next area of innovation?
2. What does it take to grow and drive innovation in the life sciences today?
3. What are the implications in the Nordics and beyond?

The Next Area of Innovation - Building on Oncology and Beyond

Innovation in life sciences and the advancement of new modalities, from antibodies and antibody constructs such as ADCs and bispecific antibodies as well as modalities beyond proteins (or ATMPs) such as cell and gene therapies has significantly been driven by oncology/hematology. And while oncology will continue to be a major area of innovation, it became clear throughout the different sessions that other areas with high unmet need and diseases related to aging such as neurology, ophthalmology or even diabetes are catching up. This is also driven by an increasingly integrated view on such diseases. Not only are companies looking at ATMPs as modalities beyond oncology, but they are combining modalities and different mechanisms of actions and adding new endpoints, biomarkers, and analytics. This was very strongly exemplified in the two supersessions that dealt with ATMPs and CNS, but also touched upon throughout the other sessions.

> ***"CNS is coming back strongly.***
>
> ***Panelist, Opportunities and challenges with new drug modalities***

After years and decades of little advancements and many disappointments, which have resulted in industry players and investors moving out of this area, CNS is back on the agenda as a therapeutic area of high interest, driven by recent breakthroughs in relevant diseases such as Alzheimer. Clearly, this therapeutic area has now reached a level of maturity that allows such breakthroughs driven by a better disease understanding through basic science leading to better target identification, better patient identification through the right biomarkers, right dose, and right efficacy endpoints (including digital biomarkers). The advancement in this area very clearly exemplifies the need for more integrated thinking and the increasing importance of pharma enabling services such as e.g. genomic diagnostics, large and well curated datasets and digital biomarkers and digital therapeutics. Key innovations include the ability to treat patients earlier, potentially even before the onset of mild cognitive impairment symptoms in Alzheimer's disease, and the integration of digital therapeutics into patients' everyday lives. By embracing these advancements and fostering collaboration, the life sciences industry is poised to make significant strides in neurological diseases and beyond, ultimately leading to improved patient outcomes and a healthier future.

We also clearly saw that new modalities are maturing even further with gene and other nucleic acid therapies making rapid advancements outside of oncology in very rare genetic disorders as well as some larger application areas in hematology. However, the field is also becoming increasingly complex, e.g., from cell and gene therapies to the potential application of heavily engineered "supercells".

> ***"We are now moving from the era of stem cell and CGT to an era of the supercell: Heavily engineered cells – engineered for efficacy, engineered for safety, engineered for manufacturing and monitoring.***
>
> ***Panelist, Opportunities and challenges with new drug modalities***

While these new treatment modalities do open the potential for curative approaches, they also raise other issues, which were discussed intensely in the new modalities' session. One of the key hurdles in this space is the cost of these drugs and how they can be reimbursed. As one panelist put it aptly "Good drugs are not making it to the market because of reimbursement". This topic is especially relevant for the potential curative approaches, which are currently coming to the market for diseases such as sickle cell anemia, but also in development for large disease areas such as diabetes. However, we do not currently know if these approaches are indeed curative as the data is still limited. Furthermore, while there are multiple models for financing under discussion, such as societal impact bonds and joint risk sharing between payors and originators, there is still an ethical dilemma whether we will be able to cure everyone. The current risk sharing models, which are in use for CAR-T and gene therapies also present additional barriers for biotech, which need to partner with large pharma to be able to afford these approaches.

> ***"Diabetes is a very important area where I hope cell therapies will make a difference.***
>
> ***Panelist, Opportunities and challenges with new drug modalities***

Growing and Driving Innovation in Life Sciences

Throughout the meeting and the different supersessions there was a common thread around how we can better grow and drive innovation in life sciences. The discussion on

the required key building blocks to grow and drive innovation was kicked off in the opening panel and supersession "From innovation to improved health: the building blocks of a successful life science sector" and continued as a theme throughout the following sessions. Specific building blocks that were mentioned were:

1. The ability to improve the support and by increasing the frequency and ease of translating academic research to companies and making the transfer of knowledge "frictionless."
2. The availability of strong sources of curated data linking outcomes to genetics and treatments, to enable better science and disease understanding, which was discussed in detail in the session on "Harnessing data to improve our health."
3. The right non-clinical models to study safety and efficacy and the ability to step away from the animal models if these are no longer appropriate, which is especially true for new modalities.
4. The ability to think in alternative approaches for clinical trials, while also not skipping e.g. the dose finding studies especially in phase 2.
5. The right network of collaborations as drug development is increasingly not only about the drugs, but also about the right diagnostics, biomarkers, data, medical technologies/devices, and other tools including the emerging AI approaches in drug discovery.

> ***"Making data tradeable will be a major shift in precision medicine.***
>
> ***Panelist, Preparing for the next unicorn: how to choose your business strategy?***

While many of these building blocks are relevant for pharma companies, as well as for biotech and start-ups, the latter also face some additional challenges. One of the key enablers that was intensely discussed in the supersession "Preparing for the next unicorn: how to choose your business strategy" was around the critical role of a clear strategy for biotech and the importance of having a well-defined plan to navigate the complex landscape of startups and established companies alike. This plan can be dynamic based on the financing environment, which was voted the most relevant influencing factor for strategy by the audience as well as internal capabilities (e.g., intellectual property) and outcomes-based scenario planning. However, a clear communication strategy and founders that are highly motivated while remaining firmly grounded are additional key success factors.

> ***"Strategy is destiny***
>
> ***Panelist, Preparing for the next unicorn: how to choose your business strategy?***

Another element that was brought up in multiple sessions is the need to collaborate early on with regulators and CDMOs. There was very clear advice that start-ups and biotech should not invest their money in production facilities, but rather look for the right CRO/CDMO that can help them with production, but also in navigating the intricacies of GMP and regulatory submissions. There were also multiple discussions on how the European Medical Agency (EMA) and regulators can help with additional funding through multiple European funds, but also advice on regulatory pathways. Especially with regards to new modalities there was strong encouragement to engage with EMA early on through scientific advice and to make use of the alternative fee structures that EMA offers for start-ups and innovators.

Lastly, there were some additional discussions on what investors and big pharma are looking for in the supersession on "The next big deal - licensing your way to success". In general, there is a trend towards earlier deals with Big Pharma looking towards biotech for upcoming innovation. In these early deals the role of a well thought

out Target Product Profile (TPP) is becoming increasingly important to attract interest and investors even in these early compounds. A comprehensive TPP should include various factors such as understanding of the treatment area, competitors, and potential combinations. By presenting a well-rounded TPP and data on pharmacokinetics/pharmacodynamics (PK/PD) and chemistry, manufacturing, and controls (CMC), companies can effectively engage with Big Pharma and foster mutually beneficial collaborations.

Nordics and Beyond

Despite all the general trends there was of course also a lot of discussion on the strength of the Nordics specifically and how the Nordics and Europe can better compete globally, while there was also acknowledgement of the global nature and strength of collaborations. The NLSDays conference highlighted the strengths of the Nordic region in the life sciences industry, emphasizing the need for confidence in their capabilities and for leveraging those unique assets to increasingly play at the global stage.

> ***Let's be more confident in who we [the Nordics] are and what we are good at.***
>
> *Panelist, From innovation to improved health: the building blocks of a successful life science sector*

The Nordics boast a high level of innovation, a significant output of companies and talent, and support from EMA. Moreover, Nordics also have had a favorable financing environment with a record $4 billion expected to be raised in 2023, according to Citeline. Another core strength of the region is the sheer abundance of data: The large amount of curated data and the ability to link that data to specific patients grants significant power to the region when e.g., making population-based decisions and propelling understanding of disease progression. By leveraging these strengths, the Nordic region can continue to impact and grow its influence on the global life sciences landscape.

> ***There is an ignorance in the global community about what we [the Nordics] have in terms of data.***
>
> *Panelist, Harnessing data to improve our health*

To maintain and enhance their position, the Nordics must continue to invest. Across the different super sessions and panel discussions, the following critical areas were identified:

- **People and talent:** Training the younger generation to not only become smart and aware but also innovative and entrepreneurial (attract, translate, mentor)
- **Clinical trial network:** Improving the network not only in the Nordics but also its relation to Europe as the Nordics and Europe are currently not attracting enough clinical trials.
- **Even better uniformity of data:** While data is one of the key strengths, it is often separated by country and sometimes even regions within a country. For better relevance this needs to be unified within countries and within the Nordics and potentially even across Europe to generate a larger and therefore more relevant data pool
- **Interpretation of GDPR:** Aligning on the definitions across the healthcare and life sciences ecosystem to enable the full usage of the curated data and not to be worried about various individual legal interpretations.

To remain competitive on the international stage, the Nordics must recognize that they are part of a global game that extends beyond regional rivalries. The Nordics bring a traditional focus on many areas such as data, but also a strong ethical perspective on topics like sustainability. It will be important to increase efforts on areas such as AI and cell therapy, to further capitalize on its strong data capabilities and to solidify its position as a leader in the life sciences industry.

> ***Setting aspirations and objectives that are achievable, and not trying to just be as big as Boston or as the Bay Area. Let's figure out what we can do here and do it .***
>
> *Panelist, From innovation to improved health: the building blocks of a successful life science sector*

Getting to Know the NLSDays 2023 Award Winners

The 2023 Merck Advance Biotech Grant Program - Nordics and the NLSDays Nordic Star 2023 Award went to Loma Therapeutics and NEUmiRNA Therapeutics, respectively. Led by Dr. Ditte Boilesen and Dr. Stephanie Holstein-Rønsbo, Loma Therapeutics is Danish biotech developing a novel immunotherapy against HPV. NEUmiRNA Therapeutics is developing RNA therapeutics for disease modification of neurological disorders with Dr. Janine Erler as the CEO.

Winner of the 2023 Merck Advance Biotech Grant Program – Nordics: Loma Therapeutics

How did you feel when you found out you had won the award?

We were very proud and happy to be chosen for the grant. It means a lot to us that the jury see the potential in our HPV treatment, and we definitely had not expected to be selected for the award in this field of incredible projects and pitches. So, gratitude and surprise sums up our feelings of that moment quite well.

What do you think were the distinguishing factor of Loma Therapeutics that won you the award?

There were a lot of really interesting companies and very good pitches, so it is of course hard to say exactly what made us stand out in the eyes of the jury, but we were very pleased that they mentioned a strong product market fit because this is something we have been working on a lot lately. Perhaps what also sets us apart is that we were presenting as a team on stage.

Winner of the NLSDays Nordic Star 2023 Award: NEUmiRNA Therapeutics

How did you feel when you found out you had won the award?

I felt deeply honoured to be selected as the Star of 2023, and very proud of what we have achieved so far! I felt grateful for the recognition of our outstanding science, team, and investment potential.

What do you think were the distinguishing factor of NEUmiRNA Therapeutics that won you the award?

Our outstanding data and team, the unmet medical need and our blockbuster drug potential. We have obtained unprecedented disease-modifying and disease-reversing data in an NIH-validated model of drug-resistant epilepsy. Our scientific co-founders are Henrik Klitgaard (developed first blockbuster drug for epilepsy) and Sakari Kauppinen (developed first miRNA targeted drug) - you cannot get stronger than that!