



Chairman's Corner:



Welcome to the summer edition of our newsletter. I hope you have been able to take some time away from work to relax and decompress from the months of restrictions placed on our normal lives due to COVID-19.

As we see the pandemic continues, Denmark, as with many other countries around the world, is facing low GDP growth in the aftermath of COVID-19. Just like the recovery following the global financial crisis in 2008-9, I firmly believe that the life science can be a major contributing factor in restoring the Danish economy. Exports of pharmaceuticals, reached 126,7 billion kr in 2019 – and has been growing by 22% month over month in the first half of 2020! Pharmaceuticals constitute the largest group of exported goods, and have been growing at the rate of 13.5% during 2013-2018. This suggests that the sector continues to hold enormous potential for further growth.

We were encouraged to see that Mr. Simon Kollerup, Minister for Industry, Business and Financial Affairs highlighted the importance of the sector to the Danish economy in a recent opinion article in [Børsen](#). Kudos to him for that and the apparent openness of the government for debate on the sector.

Mr. Kollerup held a meeting on the 25th June with the largest life science companies and organizations, including DANSK BIOTEK, to learn more from the sector about what could be done to promote further growth. It was obvious that the minister is very informed on the sector and that the policy window for supporting the life science sector is clearly open.

The ministry recently announced that eight “[Restart Teams](#)” (Da: Genstartsteams) have been established, including a team focused on life science and biotech. The common goal for the teams is to provide a list of actions that can be taken to support the Danish export and get the country financially restarted as efficiently as possible. I am very happy to see that biotech is specifically mentioned as a topic, and also that DANSK BIOTEK has been invited to participate in this important work.

The current government growth plan for life science expires at the end of 2021 and it is obvious that an ambitious follow up plan should be instigated in order to strengthen the framework conditions for the Danish life science sector.

DANSK BIOTEK strongly underlined the biotech sector's potential and has recommended the following:

- an improved basic ecosystem to support the development of new startups and the growth of established companies;
- adjustments to the tax credit scheme (skattekredit), carry-over of losses (underskudsfremførsel) and that these schemes should be linked directly to the accelerated R&D tax deduction;

- review of the effort of other countries like France, the UK and Australia for inspiration on how the biotech sector can be stimulated with targeted improvements in the R&D deduction, specifically for SMEs.

At DANSK BIOTEK we continue to work hard in our lobbying efforts to influence the government and parliament in making a successor to the growth plan for life science. I believe the impact of such a strategy will have significant benefits to the Danish economy.

Illustrating the huge growth potential and a continued maturing of the sector, several Danish companies recently filed internally developed products for regulatory approval. To ensure that the potential commercial launch is successful, some of them also raised significant funds.

In June, Ascendis Pharma's [submission of a Biologics License Application](#) (BLA) to the U.S. FDA for TransCon hGH (lonapegsomatropin) for the treatment for pediatric growth hormone deficiency (GHD) is the first product the company has taken from the idea stage to regulatory filing. TransCon hGH is a long-acting, once weekly treatment that has been designed to maintain the same mode of action as daily hGH therapies by releasing the same growth hormone molecule, somatropin. Currently, there is no approved long-acting growth hormone treatment on the market in the U.S. or Europe. Following a [successful listing of ADSs on Nasdaq](#) raising approximately \$569.2 million, Ascendis is now one of the top 100 most valuable biotech/pharma companies in the world.

Y-mabs' [submission of its BLA for omburtamab](#) for the treatment of pediatric patients with CNS/leptomeningeal metastases from neuroblastoma under the U.S. FDA's Rolling Review process was also initiated in June. Omburtamab is a monoclonal antibody that targets B7-H3, an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types.

Earlier in 2020, Zealand Pharma [submitted its first New Drug Application \(NDA\)](#) with the U.S. FDA for the ready-to-use dasiglucagon rescue pen, HypoPal[®], which is designed to offer diabetes patients fast and effective treatment for severe hypoglycemia. A potential launch in the U.S. could occur in 2021. To fund the launch, in June, Zealand [completed a private placement](#) totaling DKK 657.7 million.

Orphazyme [completed the rolling NDA submission](#) for arimocloamol to the U.S. FDA as a treatment for Niemann-Pick disease Type C (NPC), a rare inherited neurodegenerative disease caused by an accumulation of lipids (fats) in the liver, brain and spleen. The rolling NDA submission allowed Orphazyme to submit critical portions to the FDA as they were completed. The FDA has up to 60 days to determine whether to accept the application for review.

We will be resuming member meetings in the Fall and look forward to meeting our members in person again rather than via a screen!

Hans Schambye, Chairman, DANSK BIOTEK

Upcoming DANSK BIOTEK meetings

[Biotek Salon #21 - IP strategies for biotechs – Why is it important?](#)

October 1 from 14:30-17:30, COBIS, Ole Maaløes Vej 3, 2200 Copenhagen N:

Members' Meeting

As a natural consequence of COVID-19, DANSK BIOTEK had to postpone the Annual Members' Meeting scheduled for May 7 2020. We had a very interesting line up of Danish and international speakers in place, offering an exciting program. If the COVID-19 situation allows, we plan to revisit the event and reorganise this for late November. More info to follow shortly.

Read more news at www.danskbiotek.dk

All members are welcome to submit news and press releases to DANSK BIOTEK, which we publish at www.danskbiotek.dk. Topics of relevance are financing rounds, licensing deals, mergers and acquisitions, research and development news, people news, etc. As a member, feel free to submit your news to office@danskbiotek.dk.

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