INGENEIOUS

NEWS FROM COMBIGENE AB

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CombiGene – World-leading Swedish gene-therapy company

EDITORIAL:

CGT Catapult's Centre of Excellence is on the twelfth floor of Guy's Hospital, just a stone's throw from London Bridge and a fifteen-minute walk from Shakespeare's Globe Theatre.

CombiGene

The gene therapy explorer

Even optimists can be positively surprised

A lot of positive things continue to happen in CombiGene – and in the world of gene therapy. Let me start by wishing our new colleagues, Annika Ericsson (Senior Project Manager) and Anna Jönsson (CFO) a warm welcome to the company. As our epilepsy project advances and we continue to intensify our business development efforts, it is extremely gratifying to note that we have recruited two such competent co-workers. Their contribution to CombiGene's growth will be significant.

But things are moving in the right direction not only for CombiGene. Things are also happening in the wider world around us. On January 3rd Bristol-Myers Squibb, one of the world's leading drug companies, announced that they would acquire specialist pharmaceutical company Celgene for USD 74 billion. This was yet another indication of the optimism within the industry. On January 16th the next big news item was announced. The FDA (the US Food and Drug Administration) will strengthen its organization to effectively handle an expected upsurge in new gene therapy applications over the coming years.

As for our very important CG01 gene therapy project, excellent collaboration with CGT Catapult continues and the project is developing well. Don't miss the article on Catapult in this issue of Ingeneious!

I'm an optimist by nature, but things sometimes happen that I never would have imagined. One day in the autumn I was standing at Lund Central Station, waiting for the train to Copenhagen to arrive at the platform, when my telephone rang. The caller was a journalist from the renowned science magazine Nature. Suddenly, I was in the midst of a conversation about CombiGene and gene therapy that would result in a big article for which Professor Merab Kokaia, one of CombiGene's scientific founders, was also interviewed.

What pleases me most about the article in Nature is that it shows how great an interest there is in gene therapy and – not least – what an impact CombiGene and our research have started to make internationally.

The growing international interest in CombiGene is also the reason we have changed the trading platform for our share from SPOTLIGHT to Nasdaq First North, which is an internationally more well-known marketplace.

Jan Nilsson

CEO

Link to the article in Nature:
https://go.nature.com/2RGmkSV

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The company is listed on
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Please read our press releases and newsletters, available on our website.

www.combigene.com

Together with CGT Catapult we're doing our best work ever

CGT Catapult's Centre of Excellence is on the twelfth floor of Guy's Hospital, just a stone's throw from London Bridge and a fifteen-minute walk from Shakespeare's Globe Theatre.

Top row, left to right: Jan Nilsson, Anusha Seneviratne, Laxmi 'Jagan' Gurung, Adrien Soula, Mike Delahaye, Karin Agerman, Hadi Mirmalek-Sani
Bottom row, left to right: Marianne Henry, Julie Tordo, Natalie Ward, Tony Bou Kheir

Since CombiGene signed an agreement for process development with CGT Catapult in early 2018 the area around Guy's Hospital has become familiar territory for CombiGene's CEO Jan Nilsson and Karin Agerman, the company's Chief Research and Development Officer.

Ingeneious managed to catch up with Jan and Karin for an interview the day after their most recent meeting with Catapult.

About a year has passed since CombiGene signed an agreement with Catapult. How has CombiGene's CG01 epilepsy project progressed during this period?

"The work on the project is intensive," replies Jan Nilsson. "I was very pleased when we signed the agreement with Catapult and our collaboration has proceeded exactly as I had hoped it would."

"When I came to CombiGene the agreement with Catapult was already in place," adds Karin Agerman. "For me, it has been extremely inspiring to work with the very professional people at Catapult. Catapult is a British organization and, just as London is, Catapult is a mecca for international talent. I'm not sure exactly how many nationalities are represented at Catapult, but there are many. For me, this is very valuable, since it means that we in the project team gain access not only to the very best scientific quality, but also that the team has very considerable international contacts and experience."

How, more specifically, does collaboration with Catapult work?

"You could say that we have different types of contacts," explains Karin. "First of all, we have regular telephone meetings every third week. The telephone meetings are an excellent way of maintaining very precise and continuous follow-up. CombiGene and Catapult meet five or six times per year for indepth discussions on the process development, which is such an integral part of the work CombiGene and Catapult are engaged in."

Can you say how far the project has advanced?

"Like Karin said, process development is of central importance," says Jan Nilsson. "No one has ever before developed a gene therapy for epilepsy. It is therefore difficult to know exactly how long this work will take. In addition to process development, the work involves several key areas, among others, careful analysis, quality assurance and upscaling from a lab environment to GMP-certified manufacturing. We are now working intensively on the development of a manufacturing method, so as to be able to take the project to the next major step, the important biodistribution and toxicology studies."

"Another very important phase of the project is the coming transfer of technology from Catapult to the company that will produce the GMP-certified material for our future clinical studies," explains Karin. "It is decisive that this transfer is quality-assured and as smooth as possible."

Would you say that the project has thus far been problem-free?

Karin Agerman, chuckles. "That really depends on how you define problem, but if you think we can realize this development without facing some unforeseen challenges, then you're quite mistaken. You could say that problems are a part of our day-to-day work. But, together, CombiGene and Catapult form a very strong and dynamic team that can be staffed with exactly the people we need. Everyone on the team loves challenges and comes up with creative and innovative solutions. Challenges inspire all of us to do our best work ever."

Footnote: The present-day Shakespeare's Globe Theatre was built about 200 metres from the original site of the theatre. The new building opened in 1997.

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Annika Ericsson – New Senior Project Manager at CombiGene

Gene therapy is a comparatively young scientific discipline. Therefore, when CombiGene seeks to recruit new co-workers, there may be a limited number of candidates with experience from this field and even fewer candidates who hold a doctoral degree in gene therapy.

But that's exactly what CombiGene succeeded in doing when the company recruited Annika Ericsson to the position of Senior Project Manager. Ingeneious contacted Annika for a brief interview.

You recently began work at CombiGene. How has it been so far?

"It has been fantastic to start on something new again. I really enjoyed my previous job, but felt it was time to do something new and I haven't regretted the decision for a second. It's also great to be back in the gene therapy field again."

You have an academic background, we're told.

"Yes, that's correct. In 2004 I defended my doctoral thesis on a gene therapy for a disorder called acute intermittent porphyria that is characterized by deficiency of an enzyme that affects production of heme, a component of hemoglobin, the protein in red blood cells. After completing my doctorate I did a postdoc at Mount Sinai School of Medicine in New York. Since then, I have worked as Senior Scientist in the pharmaceutical industry."

What is your main task at CombiGene?

"I am project manager for our CG01 epilepsy project, which is now in a very exciting phase. Currently, I am focussed on the very extensive preparatory work that is necessary for us to be able to conduct the important biodistribution and toxicology studies. It's very exciting and I can see how much gene therapy has advanced during the past two or three years, compared to when I first started working in the field."

"I am project manager for our CG01 epilepsy project, which is now in a very exciting phase"

The growing international interest in CombiGene is also the reason we have changed the trading platform for our share from SPOTLIGHT to Nasdaq First North, which is an internationally more well-known marketplace.

CombiGene has switched to Nasdaq First North

CombiGene is active in one of the most dynamic fields of global pharmaceutical development and the company's epilepsy project is now in a very interesting phase. At the same time, CombiGene's research and development is starting to attract international attention. The article in Nature in late 2018 and the fact that CombiGene's management has received several invitations to participate in international conferences are clear indications of this. The purpose of the switch to Nasdaq First North is quite simply to create conditions for greater international interest in the company's share.

Read all of our news in one place

We would like to keep you well informed about what is happening in the company. Therefore, we are now launching CombiGene's digital newsletter to allow you to read all of our news first-hand.

Subscribe via our website, where you can register the e-mail address to which you wish the newsletter to be sent. Use the link "Subscribe to our newsletter" at the top-right corner of the page. The subscription is free of charge and you can cancel it whenever you please.

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NOTED

Bristol-Myers Squibb acquires speciality biopharma company company for 74 billion dollars

2018 was the year Big Pharma realized that gene therapy was on a roll, with several very large acquisitions of companies of their interest. 2019 will see more of the same. On January 3rd Bristol-Myers Squibb, one of the world's biggest pharmaceutical companies, announced that it would buy Celgene Corporation for USD 74 billion. Celgene's portfolio includes several exciting cell and gene therapy products. The acquisition was yet another indication of the major optimism that prevails within the field.

For many sufferers, there is no help – yet.

We hope to change this. We are in the process of developing a world-leading method for treating epilepsy. The potential is enormous, the outlook is good.

For very many people.

Events

Mars 13, 2019
Stockholm Corporate Finance
Life-science seminar
https://bit.ly/2RhSRtK

April 4, 2019
National ATMP Conference 2019, Göteborg
https://bit.ly/2QTRUeP

April 23-25, 2019
Cell & Gene Meeting on the Mediterranean 2019
https://bit.ly/2HywXCE

June 3-6, 2019
BIO International Convention, Philadelphia USA
https://convention.bio.org/2019/

September 10-12, 2019
NLSDays, Malmö
https://www.nlsdays.com/

September 10, 2019
Aktiedagen, Stockholm

October 22-25, 2019
European Society of Gene and Cell Therapy 27th annual congress, Barcelona
https://www.esgct.eu/congress/barcelona-2019.aspx

November 4, 2019
Stora Aktiedagen, Göteborg

CombiGene

The gene therapy explorer

CombiGene's objective is to develop treatment methods that can improve the quality of life for millions of people throughout the world.

www.combigene.com