



## aCROnordic Development Consulting - Your partner for a fruitful biotech investment

### Make a grounded and ambitious biotech investment

At the root of any sound biotech investment lies a qualified medical and regulatory evaluation, which can add value and nurture growth opportunities during the development of drug candidates. By unearthing the potentials, the caveats and the pitfalls during drug development, aCROnordic can help you navigate through landscapes of growth potentials.

#### Medical & Regulatory Due diligence

aCROnordic has the expertise and insight needed for a medical and regulatory due diligence of new product ideas and projects for investment. We can support you in evaluating data and asking relevant questions to assess the clinical and regulatory feasibility of the drug candidates. The answers may uncover both strengths and weaknesses of your potential biotech investment.

#### Examples of questions you may want to ask yourself

- What product category is the drug candidate at hand? Is it a new drug class?
- Will it be complicated and costly to manufacture?
- What are the regulatory requirements as to size and duration of the clinical programme?
- Will there be non-clinical requirements with impact on time to first human dose?
- What are the therapeutic needs?
- Is there an opportunity for an orphan drug or niche product with fewer requirements and shortcuts to major milestones or even registration?
- What are the opportunities and threats moving through the development phases?

#### aCROnordic is your pathfinder to the shortest and most efficient way to return on investment

aCROnordic offers in depth analysis of the therapeutic area and regulatory landscape and provides realistic, unbiased assessments on cost and timelines paving the way to a major milestone or key decision points in a development programme.

In case there is a shortcut, a therapeutic niche, or special requirements on production issues, or on human or animal studies, aCROnordic will find them and estimate the impact on time and cost of the project.

Do you want to know more on how aCROnordic can help you make the right biotech investment, please contact Executive Vice President Birgitte Guldhammer [Birgitte.Guldhammer@acronordic.com](mailto:Birgitte.Guldhammer@acronordic.com)  
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Executive Vice President  
Birgitte Guldhammer

Let us help you furnish the medical and regulatory contents upon which you can plant your decisions.

"aCRONordic has provided a competent project team to support the project of getting our advanced medicinal product into phase I. This has required an innovative approach and out-of-the-box thinking, both of which have been the result of a fruitful and productive dialogue and process with aCRONordic"

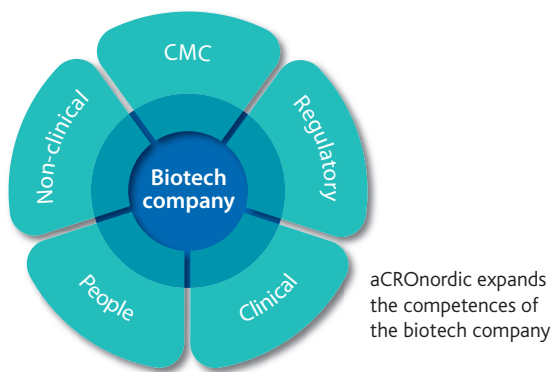
Bo Skaaning Jensen, COO, ZGene



## Bring aCRONordic expertise to your biotech investment

Development expertise is often limited in small biotech companies. By all means it is unrealistic to keep in house all the different competences required to carry a brilliant and innovative idea through the drug development phases, to major milestones or even to market. aCRONordic can offer project management and the technical and scientific expertise needed to support biotech companies.

Let us help you populate, manage, and expand the competences of your biotech companies.



### Plant the seeds on solid ground

aCRONordic can assist in defining the Target Product Profile and establishing a streamlined development programme with the shortest path to market, milestones and decision points.

#### *CMC - Chemistry, Manufacturing, and Control*

Getting the product ready for testing is a major milestone. aCRONordic can provide due diligence on documentation, assist in choice of the manufacturer, and provide audit and expertise in Quality Assurance.

#### *Non-clinical Strategy and Plan*

aCRONordic can assess the scope of animal studies requested by authorities on pharmacology, safety, and toxicology. aCRONordic can assist in the choice of supplier, as well as liaise with and manage the supplier during the process.

#### *Regulatory Strategy and Plan*

aCRONordic can assist in developing the regulatory strategy, guide the biotech in planning scientific advice and other relevant dialogue with authorities. In addition aCRONordic can prepare and collect scientific documentation prior to authority meetings and submissions.

#### *Clinical Strategy and Plan*

aCRONordic can assist in developing the clinical strategy and plan including input from international key opinion leaders, and we can identify and liaise with scientific advisory boards. aCRONordic can assist in developing protocols for the individual trials from phase I through to phase III.

#### *People - Project Managers & Team members*

aCRONordic provides experienced development project managers who can drive your projects. aCRONordic also provides experts for the key positions during the early development phases, regulatory and medical officers, drug safety advisers and experts in trial management.

Read more on our services in Development Consulting at [www.aCRONordic.com](http://www.aCRONordic.com) and feel free to contact us for more information: [Birgitte.Guldhammer@acronordic.com](mailto:Birgitte.Guldhammer@acronordic.com) or tel: +45 45168813

aCRONordic helps you harvest growth opportunities while staying grounded in your investment decisions

