Risk management

We are exposed to various risks, which may have a significant impact on our business if not properly mitigated. We frequently perform risk assessments with external partners including insurance, financial and legal advisors to maintain an up-to-date, balanced view of business-related risks. We perform an evaluation of the scientific, commercial, and financial risks on a periodic basis. Below is a summary of some of our key risks and how such risks are addressed. Please refer to note 4.4 in the financial statements for financial risks.

Strategic focus area	Key risk	What can go wrong	Impact of unfavorable outcome	Mitigating actions taken by the company
Advance our proprietary clinical pipeline of mAb mixture product candidates	Inability to prove clinical efficacy and/or safety, and obtain required regulatory approvals to commercialize the product candidates.	The product candidates may not be successful in clinical trials despite favorable results in earlier preclinical studies and clinical trials. Our development of therapeutic treatments is based on novel technologies that are unproven in a commercial context and may not result in marketable products. Regulatory agencies in Europe and the US have limited experience with mAb mixtures, which may increase the uncertainty and length of the regulatory approval process for our product candidates.	Delays or failure to complete the development of the products or if our products are not approved for commercialization as intended or additional clinical trials are required, it would materially and adversely affect our business, financial condition, results of operations and future growth prospects.	Our clinical trials are designed to prove safety and efficacy. Furthermore, we frequently consult with regulatory agencies, such as the FDA, as well as our scientific advisory Board and lead investigators who are consulted to review clinical observations and to obtain guidance on the clinical protocols and programs.
Maintaining compliance with legislation, industry codes and ethical standards	Inability to adhere to regulatory requirements pose risks of reputational damages and monetary penalties.	Our activities are subject to substantial regulation. The product candidates may not obtain regulatory approval or fulfill regulatory compliance. Even if we receive regulatory approval for a product candidate, we, our collaboration partners and the manufacturers will be subject to ongoing regulatory obligations and review. The product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval.	If any product candidate receives marketing approval and subsequently causes undesirable side effects, the ability to market the product candidates could be compromised. Adverse events, product liability lawsuits and other claims brought against us may result in substantial liabilities and we may be required to limit commercialization of our product candidates.	We have implemented multiple procedures and conduct training sessions to ensure that all regulatory requirements are considered in our operations. When entering key supplier and collaboration agreements, we perform due diligence procedures to ensure that the partner has sufficient measures in place to comply with relevant regulatory requirements.

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Commercialization of product candidates at commercially viable terms and conditions	Inability to obtain relevant market share or inadequate level of coverage and reimbursement for our product candidates by third-party payers.	The market may not be receptive to our product candidates for a variety of reasons. Competition in the biotechnology and pharmaceutical industries is intense and competitors may discover, develop, or commercialize products faster or more successfully. Lack of sales and marketing capabilities internally or through third parties may result in ineffective commercialization of the product candidates. Governments may impose restrictions on pricing or reimbursement, or cost-containment initiatives.	Any failure or delay in entering marketing and sales agreements with third parties on acceptable terms or the development of internal sales, marketing and distribution capabilities, with respect to our own product candidates would adversely impact the commercialization of such product candidates, and thus our business, financial condition, results of operations and future growth prospects.	Our clinical trials are designed to prove efficacy, thereby providing insight as to the potentially improved efficacy compared to alternative and competing therapies. Furthermore, the trials provide insights into the products safety profiles. Such data are essential to provide the stakeholders' sufficient information about the health outcome of our products to ensure commercial success.
Obtaining capital when needed on acceptable terms	Failure to obtain necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, scale back or cease our product development or any other or all operations.	We will require substantial additional financing to achieve our strategy and risk being unable to obtain the necessary capital when needed on acceptable terms. We may not be able to comply with certain agreements that require upfront, milestone, royalty, and other payments, which may require additional financing. We have never generated any revenue from product sales and may not be able to achieve profitability.	If adequate funds are not available on a timely basis, it may result in delay, limit, scale back or cease of research and development activities, preclinical studies, clinical trials, and/or the establishment and maintenance of functions and activities that may be necessary to commercialize our product candidates. Failure to comply with financing requirements could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.	While our cash and cash equivalents position at December 31, 2017 is sufficient to support our operating cash flow needs beyond December 31, 2018, it is expected that we will need to attain additional funding to support working capital needs for 2019 and beyond. We intend to finance our operations by one or more capital markets transactions or partnerships. In case that such activities are not completed, we will either seek alternative methods of finance in cooperation with our existing shareholders or revisit our strategic plans for 2019 and beyond.

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Safeguarding manufacturability of our antibody molecules and securing that material for clinical trials are readily available	Contract manufacturing organizations (CMO) may not have adequate or timely capacity or competencies and they therefore may not be available to manufacture relevant material at any given time.	We rely on third parties to manufacture our drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate. We also rely on third parties to conduct clinical trials and perform data collection and analysis, which may result in failures, additional costs and delays that prevent us from successfully commercializing our product candidates.	The loss of key suppliers, or their failure to supply, could materially and adversely affect our business, financial condition, results of operations and future growth prospects.	We have entered into a long-term agreement with CMC Biologics that provides us with preferred facility access to a clinical facility on a 12-month rolling booking structure with fixed pricing. With this agreement, we believe that we have fully secured manufacturing needs for current and planned project portfolio.
Maintaining intellectual property protection for our proprietary pipeline	We may not adequately file for patent protection or other parties may try to limit our freedom to operate or try to limit the availability of our products and technologies.	We may be unable to obtain or protect intellectual property rights related to our product candidates, or may fail to comply with our obligations under license or technology agreements. A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.	Lack of patent protection may lead to inability to compete effectively in the market. Also, third parties may assert ownership of commercial rights to inventions developed by us. This could could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Failure to comply with license or technology agreements could result in the loss of license rights or limitation of rights to develop and commercialize product candidates that are critical to the business.	We actively seek to protect the intellectual property and proprietary information and technology that we believe are important to our business. While drafting and filing patent applications, we engage third-party specialists to support this process.