

Arctic Bioscience

Operational Update Q4 2021

- Site feasibility for psoriasis phase IIb study with investigational medicinal product HRO350 complete
- Project for new GMP manufacturing facility commenced
- Full year 2021 revenues at NOK 22 million, a 7% increase from NOK 20.6 million in 2020
- Full year adjusted EBITDA of NOK -27.3 million vs NOK -20.5 million in 2020
- Year-end cash position remains solid at NOK 225.6m
- Christer Valderhaug appointed new CEO

Arctic Bioscience is a biotech company founded on the unique benefits of herring roe - with a pre-commercial pharmaceutical business and a commercial nutraceutical business. Pharma and Nutra share a proprietary technology and IP platform, including in-house R&D and value chain integration through a state-of-the-art GMP manufacturing facility.

"The fourth quarter saw many positive developments for Arctic Bioscience, particularly in pharma and technology. During the period, site feasibility has been completed, with interest from a large number of sites in Europe for participation in the phase IIb study for our drug candidate for treatment for mild-to-moderate psoriasis. The building process commenced in November for our new manufacturing facility in Ørsta, and we signed the formal contract with Smerud Medical Research for developing our second drug candidate for extremely premature infants. Nutraceutical sales were in line with our Q3 update.

Arctic Bioscience is a company like no other, using cutting edge technology to turn immature herring roe into nutraceuticals and medicines for the future, and is in an strong position to develop the company on all fronts," says CEO Ole Arne Eiksund.

Pharmaceutical development

Arctic Bioscience is developing a novel, oral drug candidate (HRO350) for the treatment of mild-to-moderate psoriasis. With approximately 90% psoriasis patients suffering from mild-to-moderate disease, the addressable market is more than 20 million patients in the USA and the EU-5 alone, corresponding to an annual revenue opportunity of more than USD 1 billion for Arctic Bioscience.

A randomized phase IIb study is scheduled to start in 2022. During the fourth quarter, approximately 80 centers in 5 European countries have been identified, and site feasibility is complete. Sufficient number of patients are secured, with enrollment scheduled for mid-2022.

In December 2021, Arctic Bioscience signed the formal agreement for the collaboration with Smerud Medical Research for development of a novel drug candidate for brain development in extremely premature infants, utilizing Arctic Bioscience's R&D capabilities and patented technology.

Technology and R&D

As part of the company's strategy to retain proprietary know-how and IP and secure control of the value chain, Arctic Bioscience is building a state-of-the-art processing facility in Ørsta, Norway. The facility is expected to improve gross margins and increase long-term company profitability.

The project is developing according to plan. Contracting requests have been published and first tenders are expected in March 2022, constituting the foundation for final conclusions on timeline and scope for the project.

Nutra

Arctic Bioscience's nutraceutical product is Romega®, an omega-3 food supplement with a unique 3:1 ratio of DHA to EPA. DHA and EPA are present in their phospholipid bound form which increases nutrient uptake. Due to its EPA content, Romega has benefits for heart health, and its high composition of DHA is especially important for brain and eye health, including prenatal development. To capitalize on Romega's high content of DHA, a new B2C product, Romega Brain, was launched in Norway H2 2021 and is expected to drive B2C sales in Norway going forward.

Products are sold through B2C and B2B channels globally, and the Arctic Bioscience has an established partnership with Kotler Marketing Group for distribution in the Chinese market.

Kotler has initiated several marketing initiatives to broaden outreach for Romega® products in China. In addition, Kotler has initiated a nutraceutical intervention study to map uptake of DHA with pregnant women.

Financials

Key Financials (NOK million)	Q4 2021	Full Year 2021
Revenue	5.3	22.0
Gross Profit	2.7	7.1
EBITDA	(8.9)	(36.1)
Adjustments *	-	(8.8)
Adjusted Gross Profit	2.7	7.7
Adjusted EBITDA	(8.9)	(27.3)
Capex	9.0	35.4
Cash at end of period	225.6	225.6

** Adjustments to operating expenses are made for costs associated with the listing on Euronext Growth as well as a non-recurring cost related to change in distributor relationship in USA*

Sales revenues during the fourth quarter amounted to NOK 5.3 million, with FY revenue of NOK 22 million, somewhat below expectations.

Bulk sales were in line with forecast for Europe, but slightly below expectations for the Americas. Sales of finished goods in China have progressed in line with the intentions in the collaboration with Kotler. Restrictions associated with the COVID pandemic continue to have an impact on the company's ability to meet with clients, especially in the US. COVID-related delays at the company's capsule producer have also slowed supply and thus sales of European and Chinese finished goods during Q4 2021, with part of these sales now postponed to early 2022. On the positive side, the company is taking advantage of the recent reopening for travel and attending important international trade shows, increasing the number of qualified customer leads for 2022.

Adjusted EBITDA for the quarter amounted to NOK -8.9 million, in line with forecast, leaving FY adjusted EBITDA at NOK -27.3 million.

Total capital expenditures (CAPEX) amounted to NOK 9.0 million during the quarter, mainly related to the phase IIb clinical development program. FY CAPEX totals NOK 35.4 million.

Following the capital raise in February 2021, the company maintains a solid financial position with liquidity to fund ongoing and planned projects through 2023. At the end of the fourth quarter, the company's cash and cash equivalents amounted to NOK 225.6 million.

Subsequent events

In January, the company announced the appointment of Christer Valderhaug as new CEO, succeeding Ole Arne Eiksund who has been managing the company since 2018. Mr. Valderhaug will join Arctic Bioscience from his position as partner and head of investments at the advisory firm Convento AS.

Bringing experience from capital markets and managing and advising growth companies, Mr. Valderhaug will lead the next phase of the transition of Arctic Bioscience, from a marine ingredients business to capture the strong growth and value creation potential in nutraceutical and pharma applications. Mr. Valderhaug will join the company 1 March 2022.

Also in January, CFO Danielle Glenn terminated her consulting agreement with Arctic Bioscience to pursue business opportunities outside the company. The search for a new permanent CFO has been initiated.

Outlook

Arctic Bioscience will continue to pursue its drug development programs in the pharmaceutical business, and revenue growth and profitability within its nutraceutical business.

Following the positive response from sites, the company will have access to patients to initiate the phase II study for HRO350 mid-2022. Based on successful completion of the study, the company plans to run a Phase III clinical trial in collaboration with a commercial partner, with plans to apply for marketing authorization from the European Medicines Agency (EMA) and the Food & Drug Administration (FDA) thereafter.

The outlook for nutra in 2022 is strong with revenue expected to be in the range of NOK 30-40 million and consolidated company EBITDA expected to be in the range of NOK -30 to -40 million.

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About Arctic Bioscience

Arctic Bioscience is a biotech company developing and commercializing nutraceutical products based on herring roe oil. Herring roe oil contains lipids that are essential to maintain cell membranes, contributing to normal functioning of brain, heart, and vision. Nutraceuticals from Arctic Bioscience are sold globally as bulk ingredients to other companies making dietary supplements, and as finished goods under the Romega brand. The strategy is to switch sales from bulk to finished goods and focus markets are USA and China.

The company is developing HRO350 – a novel investigational drug candidate with herring roe as raw material. HRO350 is being developed for treatment of mild-to-moderate psoriasis. This is a large patient group in need of new effective medicines with beneficial safety profile. Arctic Bioscience is led by a team of highly competent people with experience in developing marine oils and experience from global pharmaceutical companies.