

Arctic Bioscience Q3 2021 Operational Update

- Psoriasis phase IIb study for HRO350 on track: site feasibility process ongoing in Europe as planned with positive response from sites with access to patients for H1 2022.
- New GMP manufacturing facility in Ørsta: Building process commenced, with planned finalization H2 2023. In-house manufacturing of our nutraceutical and investigational pharmaceutical products is expected to significantly improve company-wide gross margins.
- Full year adjusted EBITDA forecast in expected range of NOK -25 to -30 million
- Year-end cash position remains very solid, forecast in the range of NOK 200 to 220 million.

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 third quarter saw many positive developments for Arctic Bioscience, particularly in pharma and technology. During the period, site feasibility has been ongoing, 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. We expect to initiate the study during the first half of 2022 according to plan. We are also happy to announce the building process has commenced for our new manufacturing facility in Ørsta, which will support both the pharmaceutical and nutraceutical businesses when finalized. While nutraceutical sales have been slower than expected in this unusual year, we remain in an excellent position to develop the company further on all fronts", says CEO Ole Arne Eiksund in Arctic Bioscience.

Pharmaceutical

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 the company.

A large, randomized phase IIb study scheduled to start in 2022. During the third quarter, site feasibility has been ongoing and a large number of sites in Europe have been identified for the phase IIb study. First patient is planned to be enrolled in the study during H1 2022.

In addition to HRO350, Arctic Bioscience has entered a collaboration with Smerud Medical Research for the development of a novel drug candidate for brain development in extremely premature infants, utilizing Arctic Bioscience's R&D capabilities and patented technology. SkatteFUNN has been granted and the project is developing according to plan. A market analysis report has been commissioned to provide financial projections for the potential use of such a drug.

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 will significantly improve gross margins and increase long-term company profitability. The project is developing according to plan, with building work begun in August 2021 and planned finalization in the second half of 2023.

Nutraceutical

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

In Q3, the company launched the new B2C product Romega Brain to capitalize on Romega's high content of DHA. Romega Brain is expected to drive significant B2C sales growth going forward. The company also announced a collaboration with neuroscientist Ole Petter Hjelle, MD PhD, to provide scientific and research-based knowledge in support of the company's activities pertaining to brain health.

Financials

Key financials (NOK million)	Q3 2021	YTD 2021
Revenue	4.8	16.8
Gross profit	1.0	4.4
EBITDA	(7.4)	(27.4)
Adjustments *	-	(8.8)
Adjusted gross profit	1.0	5.0
Adjusted EBITDA	(7.4)	(18.6)
Capex	3.9	25.7
Cash at end of period	246.5	246.5

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

Sales revenues during the third quarter amounted to NOK 4.8 million, with YTD revenue of NOK 16.8 million slightly below expectations. Bulk sales were in line with forecast for Europe but slightly below expected for the Americas. Sales of finished goods in China were slightly better than expected and 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 will also slow supply and thus expected 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 during the quarter amounted to NOK -7.4 million. This was in line with the company's Q3 forecast and leaves YTD adjusted EBITDA at NOK -18.6 million, slightly ahead of budget.

Total capital expenditures (CAPEX) amounted to NOK 3.9 million during the quarter, mainly related to the phase IIb clinical development program. CAPEX YTD totals NOK 25.7 million, slightly below budgeted, but all planned projects remain on track.

Following the capital raise in February, the company maintains a very solid financial position with liquidity to fund ongoing and planned projects through 2023. At the end of the third quarter, the company's cash and cash equivalents amounted to NOK 246.5 million.

Subsequent events

In an extraordinary general assembly of shareholders on 10 November, Marita Holstad was elected as new board member of the company. Marita Holstad has extensive experience from the pharmaceutical industry, including work in the psoriasis space, and is currently Global Vice President, Commercialization Leader

respiratory in GlaxoSmithKline (GSK), based in Chicago, IL. Before joining GSK, Marita Holstad has 16 years' experience from AbbVie (previously Abbott) within Immunology management positions in Norway, UK and the US across Rheumatology, Gastrology and Dermatology. Holstad holds an MBA degree in Strategic Leadership from the Norwegian School of Economics and Business Administration (NHH).

In her previous work, Maria Holstad has gained relevant capabilities and experience in developing and bringing pharmaceutical products to market, including within the field of psoriasis, and her combined strategic, operational and cross-functional experience is well aligned with Arctic Bioscience's roadmap going forward.

In October, Arctic Bioscience was granted a U.S. patent with a new method related to type II diabetes. Building a portfolio of patents is crucial to safeguard Arctic Bioscience's ongoing development programs and an important part of the strategy to protect the company's IP. In addition to securing exclusive rights for utilization of the technology in other areas, it also represents an opportunity for possible future new business areas for Arctic Bioscience.

Outlook

Arctic Bioscience will continue to pursue its drug development programs in the pharmaceutical business, and revenue growth and profitability within its nutraceutical business. Due to pandemic related operational and logistical challenges at our subcontractors, the company expects full year revenue in the NOK 20 to 25 million range. Despite lower revenue projections, adjusted EBITDA is expected to end the year in line with forecast of NOK -25 to -30 million. Importantly, the expected cash position at the end of the year is forecast to be higher than expected at around NOK 200 to 220 million.

Following the positive response from sites, the company will have access to patients to initiate the phase II study for HRO350 during H1 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.

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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. Arctic Bioscience is led by a team of highly competent people with experience in developing marine oils and experience from global pharmaceutical companies.