Flash Note

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BIOCELTIX (BCX PW; BUY; TP PLN 120)

1H26 earnings call takeaways: Clinical progress remains intact, while risks shift towards CMC and financing [neutral]

- 1H26 results: The company reported a net loss of PLN 10.8m vs. PLN 7.4m a year earlier, with OCF of PLN -8.7m. Cash at end-June stood at PLN 56.8m. Rising operating expenses and CAPEX related to the new manufacturing facility are putting increasing pressure on cash runway.
- BCX-CM-J (canine osteoarthritis): In May 2026, the company submitted responses to the EMA's previous questions and received a List of Outstanding Issues (LoOI) on 16 July. The remaining work includes expanding quality control methods and revalidating the manufacturing process. At this stage, the EMA has not requested an additional clinical trial.
- EMA timeline: The company plans to submit its complete responses by 18 May 2027 at the latest, potentially allowing for a CVMP recommendation on 17 June 2027 and an EC decision in August 2027. Earlier completion of CMC activities could accelerate the process, subject to the availability of EMA assessment slots.
- BCX-CM-AD (canine atopic dermatitis): The clinical phase of the project was completed in 2025. In March 2026, the company presented long-term follow-up data extending to approximately Day 168, showing sustained reductions in skin lesions measured by CADESI-4 and pruritus measured by PVAS, with a safety profile consistent with the main study period. The company intends to pursue registration through an indication extension following the approval of BCX-CM-J.
- BCX-EM (equine osteoarthritis): The project is undergoing EMA registration review. The clinical trial met both its primary and secondary endpoints. Additional analyses covering approximately three months after administration demonstrated a sustained treatment effect, including improvements in lameness, pain and joint swelling.
- Commercialisation / partnering: The company remains at the pre-commercial stage. Its commercialisation strategy envisages cooperation with global animal health companies through partnering, licensing or distribution agreements, preferably while retaining manufacturing in-house. Discussions with potential partners are ongoing. Since April 2026, Bioceltix has also been working with an adviser on its US regulatory strategy and preparations for formal engagement with the FDA's Center for Veterinary Medicine (CVM).
- New manufacturing facility: Construction of the approximately PLN 61m facility is progressing, although disbursement of the PLN 17.4m PARP grant remains conditional, among other things, on BCX-CM-J registration. In 1H26, the company obtained the environmental decision and building permit. Following the reporting period, the building permit became final, and on 4 August 2026 the company signed a contract for the steel structure and mezzanine floors. Delays in registration and the signing of a binding partnering agreement with an upfront payment, against the current cash runway estimated to extend into 2Q27, will increase the risk of additional capital requirements.

Comment: *We assess the overall newsflow as neutral. Clinical results across all three projects confirm the company's technological capabilities, while the nature of the EMA's outstanding questions reduces concerns regarding BCX-CM-J efficacy. The key issue remains the ongoing EMA review of BCX-CM-J. The formal timeline now points to submission of responses and a potential CVMP recommendation towards the end of 1H27. However, in our view, the nature of the questions received from the EMA in July 2026 does not currently suggest new efficacy or safety concerns or the need to repeat clinical trials, with the remaining work primarily focused on CMC and quality control. Accordingly, we believe BCX may be able to submit its responses ahead of the May 2027 deadline.* ***# Valuation and TDM outlook:*** *We maintain our financial forecasts and TP.* ***# Key newsflow****: 1) BCX-CM-J – completion of additional QC analyses and manufacturing process revalidation over the coming months; responses to the EMA by 18 May 2027 at the latest; potential CVMP recommendation on 17 June 2027; 2) BCX-EM – further developments in the EMA registration process (2H26/1H27); 3) BCX-CM-AD – preparation of the regulatory pathway as an indication extension to BCX-CM-J (2027); 4) Partnering – potential BCX-CM-J distribution agreement (2H26/1H27); 5) US – initial outcomes of regulatory engagement with the FDA/CVM (2H26).*

 # Financing**: The company's current cash runway extends to the end of 2Q27. The postponement of registration to 2H27, substantial CAPEX requirements for the new facility and the absence of a partnering agreement increase financing risk. The key share price catalysts remain completion of CMC activities, a positive CVMP recommendation and the signing of a commercialisation agreement with a meaningful upfront payment, which could reduce the need for an equity raise. **(Katarzyna Kosiorek)

PLNm	2023	2024	2025	2026E	2027E	2028E
Revenues	0	0	0	0	59	84
EBITDA	-15	-18	-15	-23	52	57
EBIT	-16	-19	-15	-24	48	52
Net profit	-14	-15	-15	-24	38	42
EPS (PLN)	-3.3	-3.0	-3.1	-4.3	7.0	7.5
P/E (x)	-	-	-	-	10.1	9.3
EV/EBITDA (x)	-	-	-	-	6.3	5.1
FCFF Yield (%)	-12.8%	-19.5%	-23.0%	-11.6%	9.8%	13.1%
DY (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Company, Trigon

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