

Flash Note

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Bioceltix (BUY; PLN 128.4)

2Q26 results: financial results close to expectations; BCX-CM-J registration process and response to EMA LoOI remain key [neutral]

PLNm	2Q25	3Q25	4Q25	1Q26	2Q26	Y/Y	Q/Q	2Q26E	Cons.
Revenues	0.0	0.0	0.0	0.0	0.0	-	-	0.0	0.0
MSC-based therapies	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Costs	3.7	4.3	4.7	6.1	5.5	0.0	0.0	5.1	
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Gross profit	-3.7	-4.3	-4.7	-6.1	-5.5	0.0	0.0	-5.1	
Other operating profits/costs	0.0	0.0	1.3	0.4	0.5	0.0	0.0	0.0	
EBITDA	-3.5	-4.1	-3.3	-5.6	-4.8	-	-	-4.9	-5.3
D&A	0.2	0.2	0.2	0.2	0.2	0.0	0.0	0.2	
EBIT	-3.7	-4.3	-3.4	-5.8	-5.0	-	-	-5.1	-5.5
Net financial costs	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.1	
EBT	-3.7	-4.3	-3.4	-5.7	-5.1	0.0	0.0	-5.0	
Income tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Minority interest	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Net profit	-3.7	-4.2	-3.4	-5.7	-5.1	-	-	-5.0	-5.4
OCF	-1.9	-5.0	-4.5	-6.2	-2.5				
Net cash	30.0	24.0	68.4	60.8	56.8				
P/E12Mtrailing	-	-	-	-	-				
EV/EBITDA 12M trailing	-	-	-	-	-				
EBITDAmargin	-	-	-	-	-				
EBIT margin	-	-	-	-	-				
Net profit margin	-	-	-	-	-				

Source: Company, Trigon DM

- **Operating costs:** PLN 5.5m (+47% y/y; +15% q/q). The q/q cost structure reflected: 1) lower external services costs (PLN 2.1m; +38% y/y; -14% q/q); 2) lower materials and energy costs (PLN0.6m; +11% y/y; -42% q/q); and 3) a slight increase in personnel costs (PLN 2.0m; +36% y/y; +8% q/q).

- **Grant income:** PLN 0.5m (vs PLN0.4m in 1Q26 and PLN0.1m in 2Q25).

- **R&D status: 1) BCX-CM-J** (osteoarthritis in dogs): in May'26, the company submitted responses to EMA's previous questions, and on 16 July received a List of Outstanding Issues (LoOI). Further work includes, among others, expanding quality-control methods and revalidating the manufacturing process. At this stage, EMA has not indicated the need for an additional clinical trial. The company plans to obtain a formal deadline of 18 May 2027 for submitting its responses, with the current timeline allowing for a potential CVMP recommendation on 17 June 2027.

2) BCX-CM-AD (atopic dermatitis in dogs): the clinical stage of the project was completed in 2025. In March'26, the company presented long-term follow-up data through approximately Day 168, showing a sustained reduction in skin lesions measured by CADESI-4 and pruritus measured by PVAS, with the safety profile consistent with the primary study period. The company plans to pursue registration as an indication extension of BCX-CM-J.

3) BCX-EM (osteoarthritis in horses): the project is undergoing the EMA registration procedure. The clinical trial met its primary and secondary endpoints. Additional analyses covering approximately three months after administration showed a sustained treatment effect, including improvements in lameness, pain and joint swelling.

- **Commercialisation / partnering:** BCX remains at the pre-commercial stage. Its commercialisation model assumes cooperation with global animal-health companies through partnering, licensing or distribution agreements, with BCX preferring to retain manufacturing in-house. Discussions with potential partners are ongoing. Since April'26, the company has also been working with an advisor on its US regulatory strategy and preparations for formal dialogue with the FDA/CVM.

- **New manufacturing facility:** the project to construct a new facility on Skrzypowa Street is valued at approximately PLN61m, with maximum grant funding of PLN17.4m. In 1H26, the company obtained the environmental decision and building permit; following the end of the reporting period, the permit became final, and on 4 August'26 BCX signed an agreement for the construction of the steel structure and mezzanines.

Comment: We view the 2Q26 results as neutral and expect a similar market reaction. **# Results:**

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EBITDA was in line with our expectations, while PLN56.8m of cash as of end-June 2026 provides a relatively comfortable financial position at the current stage of development. The key development remains the LoOI for BCX-CM-J: the formal timeline now assumes submission of responses and an EMA recommendation towards the end of 1H27. However, in our view, the nature of the EMA questions received in July'26 does not currently indicate new efficacy/safety issues or the need to repeat clinical trials, with the remaining work focused primarily on CMC/quality. We therefore assume that BCX may submit its responses to EMA earlier than May'27. # **TDM valuation and outlook:** we maintain our financial assumptions and TP. The next key validation point will be the completion of additional analytical/revalidation work and submission of responses to EMA; under the current timeline, the CVMP recommendation is scheduled for June'27. A positive resolution of the quality/CMC issues should also increase the project's value in the ongoing partnering discussions. # **Key project newsflow:** 1) BCX-CM-J – additional QC analyses and manufacturing-process revalidation over the coming months; response to EMA by 18 May 2027 at the latest; potential CVMP recommendation on 17 June 2027; 2) BCX-EM – further progress in the EMA registration process (2H26/1H27); 3) BCX-CM-AD – preparation of the regulatory pathway as an indication extension of BCX-CM-J (2027); 4) partnering – potential BCX-CM-J distribution agreement (2H26/1H27); 5) US – initial outcomes of the regulatory dialogue with FDA/CVM (2H26). The company's current cash runway extends to end-3Q27. **(Katarzyna Kosiorek)**

PLNm	2023	2024	2025	2026E	2027E	2028E
Revenues	0.0	0.0	0.0	0.0	59.5	84.1
EBITDA	-15.4	-18.3	-14.6	-22.7	52.3	57.2
EBIT	-15.8	-18.8	-15.2	-23.7	48.2	52.0
Net profit	-13.7	-14.9	-15.2	-23.7	38.5	41.6
EPS(PLN)	-3.3	-3.0	-3.1	-4.3	7.0	7.5
P/E(x)	-	-	-	-	10.8	10.0
EV/EBITDA (x)	-	-	-	-	6.9	5.6
P/BV (x)	-	9.7	5.1	8.4	4.7	3.2
DY (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Company, Trigon

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