Flash Note

CEE | Equity Research

Bioceltix (Buy; 128.4 PLN)

Assessment of the EMA list of questions for BCX-CM-J; responses planned by May 2027 [slightly negative]

- The Management Board has completed its assessment of the list of questions received from the EMA as part of the BCX-CM-J marketing authorization procedure and concluded that their scope is consistent with expectations and the standard course of the regulatory review; the Company did not identify any new issues requiring a material change to its regulatory strategy.

- According to the Company's regulatory advisor, the number of questions is relatively limited compared with similar marketing authorization procedures. In addition, the EMA did not raise any further comments regarding the potency marker, which, in the Company's view, may indicate that its previously submitted explanations have been deemed satisfactory.

- The remaining work is primarily focused on the development and validation of additional analytical methods for quality control, as well as the revalidation of the manufacturing process following their implementation. All other questions will be addressed in parallel and are not expected to determine the timing of the Company's response.

- The Company expects to complete the required work within approximately six months; however, as a precautionary measure, it intends to request that the EMA sets 18 May 2027 as the official deadline for submitting the complete response package. Assuming this timeline is maintained, the CVMP opinion could be issued on 17 June 2027, followed by the European Commission's marketing authorization decision approximately 67 days later, in line with the standard regulatory procedure.

Comment: *We view the announcement as slightly negative. On the positive side, management indicated that the EMA's List of Questions does not contain any issues beyond the standard scope of the regulatory review and, importantly, includes no additional comments regarding the potency marker, which represented the key concern raised during the first review cycle. However, the planned submission date for the Company's responses—18 May 2027—is later than our expectations. Although the delay appears to be driven by the technical complexity and time requirements associated with developing and validating additional analytical methods, the updated timeline postpones the regulatory process by approximately one quarter relative to our previous assumption of 4Q26/1Q27.*

#Valuation: *At this stage, the announcement primarily delays the expected commercial launch of BCX-CM-J by several months, resulting in a modest negative impact on our valuation, which we estimate at no more than approximately PLN 6 per share. More importantly, the revised regulatory timeline brings the expected commercial launch materially closer to the Company's projected cash runway (2H27). Should the registration process experience any additional delays, we cannot rule out the possibility that Bioceltix may require additional financing before reaching commercialization. We note, however, that the proposed 18 May 2027 submission date represents, in our view, a conservative upper-bound timeline, and we do not exclude the possibility that the Company may submit its responses to the EMA earlier than currently indicated.* ***(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	47	51
Net profit	-14	-15	-15	-24	38	41
EPS (PLN)	-3.3	-3.0	-3.1	-4.3	6.8	7.4
P/E (x)	-	-	-	-	11.9	11.0
EV/EBITDA (x)	-	-	-	-	7.6	6.3
FCFF Yield (%)	-11.0%	-16.6%	-19.2%	-11.5%	8.1%	10.6%
DY (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Company, Trigon

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