Flash Note

CEE | Equity Research

Bioceltix (BUY; PLN 128.4)

BCX-CM-J EMA registration update: no major safety/efficacy concerns; remaining work focused primarily on quality control and manufacturing process [positive]

 # EMA / Scope of questions:
- Following its review of the List of Outstanding Issues, management believes that the nature and scope of the EMA's questions are in line with expectations and do not require any fundamental change to the regulatory strategy.
- According to Bioceltix's regulatory advisor, the number of questions is relatively limited compared with similar registration procedures. Importantly, the EMA raised no further comments regarding the potency marker, which, according to the company, may indicate that the explanations provided to date were considered sufficient by the reviewers.

 # Key outstanding issues:
- The EMA's questions are focused primarily on two areas: (1) expanding quality control to include additional analytical methods, which need to be developed and validated – the most time-consuming work has already been outsourced to a specialized third party; and (2) revalidation of the manufacturing process following implementation of the required changes.
- The remaining questions and comments will be addressed in parallel and, based on the company's current assessment, are not expected to determine the timing of the EMA response.

 # Timing – response to the EMA:
- The company estimates that preparing the complete set of responses should take approximately six months. However, to provide an adequate safety buffer, it intends to request a formal submission deadline of 18 May 2027 from the EMA.
- Management describes this deadline as conservative and sees scope to complete the work earlier and request an earlier submission slot from the EMA, subject to availability.

 # Next regulatory steps:
- Assuming the 18 May 2027 submission deadline is maintained, the regulatory timetable provides for a CVMP recommendation on 17 June 2027. If the recommendation is positive, the European Commission generally issues its Marketing Authorisation decision within 67 days, implying a potential EC decision around 23 August 2027.
- As a result, the current formal timeline shifts the potential Marketing Authorisation (MA) for BCX-CM-J to 3Q27, vs previous expectations of a potential positive EMA recommendation by the end of 2026.

 # Key dates:
~6 months – estimated time required by the company to complete the necessary work;
18 May 2027 – conservative deadline for the EMA response that BCX intends to request;
17 June 2027 – scheduled CVMP recommendation;
~23 August 2027 – indicative EC decision date, assuming a positive CVMP opinion and the full 67-day review period.

Comment: *We view the update positively, despite the formal BCX-CM-J registration timeline being pushed back to the end of 1H27. The scope of the EMA's questions does not currently indicate any new efficacy/safety concerns or the need for additional clinical trials, with the remaining work focused primarily on relatively predictable CMC/quality matters. At the same time, the company is entering the final stages of the regulatory process against a supportive backdrop for the animal health market and growing interest in innovative veterinary therapies, which should support ongoing partnering discussions.*

 # Valuation / financing: *In our 31 July 2026 comment, we indicated that a c. 6-month delay in the BCX-CM-J registration timeline would reduce our valuation by approximately PLN 6/share, and we currently maintain this view. From a financing perspective, an important takeaway from the conference call was the relatively near-term prospect of a potential BCX-CM-J partnering deal, which could provide both commercial validation of the asset and funding ahead of commercialization. The risk of an equity raise remains in an extremely negative EMA interaction scenario; however, this could be mitigated through upfront and milestone payments from a partnering agreement, as well as other non-dilutive financing options. As a result, a key share price catalyst over the coming quarters could be not only progress on the work required by the EMA, but particularly a partnering transaction, which could simultaneously reduce commercialization risk and the need to raise equity.*

#TDM view: *BCX is entering the final stages of the regulatory de-risking of BCX-CM-J. The key issues from here are the timing of the response submission to the EMA and whether the company can complete the process without additional studies, which we currently view as likely. No additional rounds of material questions and maintaining the path towards Marketing Authorisation would represent a meaningful positive catalyst, while also providing further validation for the company's second asset, BCX-CM-AD, and Bioceltix's broader MSC platform.* ***(Katarzyna Kosiorek)***

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