

Bioceltix

Closer to the registration of the first product with EMA

3Q24 Results Outlook: Neutral

For the quarter, we anticipate an OPEX level of around PLN 6.0m. For the full year 2024, we expect R&D costs to be around PLN 23m.

Projects status:

- **BCX-CM-J (drug for joint degeneration in dogs):** In 1H24, the project completed a key stage of clinical development, confirming therapeutic efficacy and a good safety profile. The company submitted an application to the EMA for market approval in May 2024. In August 2024, BCX also received an extension of its GMP certification for manufacturing the medicinal product for commercial purposes. The company received its first feedback from the EMA on October 18, 2024, with no serious issues identified that would hinder the registration process.
- **BCX-CM-AD (drug for atopic dermatitis in dogs):** The project is currently in the clinical trial phase with patients, with results expected by the end of 2024. In July 2024, BCX provided information on the interim analysis results. At the start of the clinical trial, the total number of patients was estimated at around 120, but the analysis allowed the final number of participants to be set at 84. BCX estimates that the clinical trial report and the EMA application will be available in 1H25.
- **BCX-EM (drug for arthritis in horses):** The project is in a critical stage of clinical development. In September 2024, BCX announced preliminary product readings confirming the effectiveness of osteoarthritis therapy in horses. The primary efficacy criterion was achieved by 64.1% of the horses receiving BCX-EM and 33.3% of the control group. The result is statistically significant. Success in the primary endpoint, measured on day 283 after product or placebo administration, was defined as a reduction in lameness from level 2 (visible lameness during straight-line movement) or 3 (clearly visible lameness in all gaits) on the AAEP scale to level 0 (no lameness) or 1 (minimal, hard-to-detect lameness). Final readings are planned for the end of 2024, with a regulatory submission to the EMA expected in 1Q25.
- No one-off events are expected in the quarter.
- We expect a slightly positive market reaction to the results.

PLNm	3Q22	4Q22	1Q23	2Q23	3Q23	4Q23	1Q24	2Q24	3Q24E	y/y	q/q
Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0%	0%
EBITDA	-2.7	-2.7	-2.5	-3.7	-3.6	-3.8	-4.1	-4.0	-5.9	-	-
EBIT	-2.8	-2.8	-2.6	-3.8	-3.7	-4.0	-4.2	-4.2	-6.0	-	-
Net profit	-2.8	-2.8	-2.6	-3.8	-3.5	-3.8	-4.2	-4.2	-6.1	-	-
P/E12M trailing	-	-	-	-	-	-	-	-	-	-	-
EV/EBITDA 12M trailing	-	-	-	-	-	-	-	-	-	-	-
revenues growth y/y	-	-	-	-	-	-	-	-	-	-	-
EBITDA margin	-	-	-	-	-	-	-	-	-	-	-
EBIT margin	-	-	-	-	-	-	-	-	-	-	-
Net profit margin	-	-	-	-	-	-	-	-	-	-	-

Buy

(Previous: Buy;129.8PLN)

Target Price: 129 PLN

Current Price: 72.5 PLN

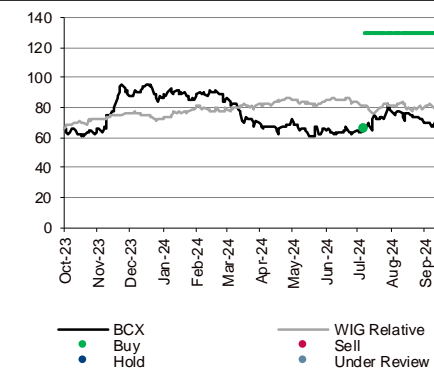
Upside: 78%

3Q24 Earnings
25/11/2024

FACT SHEET		RECOMMENDATIONS	Date	Valuation
Ticker	BCX	Buy	29/07/2024	129.8
Sector	Biotechnology			
Price (PLN)	72.5			
52W range (PLN)	59 / 98			
Shares outstanding (m)	4.9			
Market Cap (PLNm)	357			
S&P Global ESG Scores	-			
3M Avg. Vol. (PLNm)	0.45			
Price perf.	1M	3M	1Y	
	-0.7%	13.8%	9.2%	

P/E 12M vs EV/EBITDA 12M

BCX RELATIVE SHARE PRICE vs WIG



PLNm	2021	2022	2023	2024E	2025E	2026E
Revenues	0	0	0	0	36	18
EBITDA	-6	-9	-15	-22	27	11
EBIT	-6	-10	-16	-23	25	7
Net profit	-4	-9	-14	-18	24	2
EPS (PLN)	-2.60	-2.6	-3.3	-4.4	5.9	0.4
DPS (PLN)	0.0	0.0	0.0	0.0	0.0	0.0
P/E (x)	-	-	-	-	12.3	193.2
EV/EBITDA (x)	-	-	-	-	10.4	25.0
P/BV (x)	48.2	48.2	28.6	8.6	5.1	4.9
DY (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Quarterly update 3Q24

CEE | Equity Research

Valuation / Weight	Current		Previous		Change	
rNPV	129.0	0%	129.8	0%		-1%

PLNm	2024E			2025E			2026E		
	Curr.	Prev.	Chg.	Curr.	Prev.	Chg.	Curr.	Prev.	Chg.
Revenues	0	0	-	36	36	0%	18	18	0%
EBITDA	-22	-22	-	27	27	0%	11	11	0%
EBIT	-23	-23	-	25	25	0%	7	7	0%
Net profit	-18	-18	-	24	24	0%	2	2	0%
P/E (x)	-	-	-	14.6	14.6	-	229.7	229.7	-
EV/EBITDA (x)	-	-	-	12.5	12.5	-	30.0	30.0	-
P/BV (x)	10.2	-	-	6.0	-	-	5.9	-	-
DY (%)	0.0%	-	-	0.0%	-	-	0.0%	-	-

Multiples	2022	2023	2024E	2025E	2026E
P/E (x)	-	-	-	12.3	193.2
adj. P/E (x)	-	-	-	12.3	193.2
P/BV (x)	48.2	28.6	8.6	5.1	4.9
EV/EBITDA (x)	-	-	-	10.4	25.0
adj. EV/EBITDA (x)	-	-	-	10.4	25.0
EV/Sales (x)	-	-	-	7.9	15.7
FCF Yield (%)	-2.3%	-4.4%	-	-	-
DY (%)	0.0%	0.0%	0.0%	0.0%	0.0%

KPIs	2022	2023	2024E	2025E	2026E
EPS (PLN)	-2.6	-3.3	-4.4	5.9	0.4
adj. EPS (PLN)	-2.6	-3.3	-4.4	5.9	0.4
DPS (PLN)	0.0	0.0	0.0	0.0	0.0
BVPS (PLN)	1.5	2.5	8.4	14.3	14.7

Operational ratios	2022	2023	2024E	2025E	2026E
Gross margin (%)	-	-	-	28.9%	60.3%
adj. EBITDA margin (%)	-	-	-	75.8%	63.1%
EBIT margin (%)	-	-	-	71.1%	39.7%
Net profit adj. margin (%)	-	-	-	68.2%	8.8%

ROE (%)	-160.0%	-175.3%	-80.8%	51.7%	2.6%
ROA (%)	-112.6%	-134.3%	-65.3%	34.9%	1.6%
CAPEX/Sales (%)	-	-	-	90.9%	11.3%
CAPEX/D&A (x)	0.8	1.1	7.9	19.7	0.5
Net debt/Equity (x)	-0.8	-0.9	-0.2	-0.3	-0.4
Net debt/EBITDA (x)	0.4	0.6	0.4	-0.7	-2.0

Cash conversion cycle (days)	-	-	-	47	251
Inventory turnover (days)	-	-	-	128	513
Receivables turnover (days)	-	-	-	21	44
Payables turnover (days)	-	-	-	102	306

IncomeStatement(PLNm)	2021	2022	2023	2024E	2025E	2026E
Revenues	0	0	0	0	36	18
Revenues from MSC-based therapies	0	0	0	0	36	18
Operating costs	6	10	16	23	10	11
COGS	0	0	0	0	1	6
Profit from sales	-6	-10	-16	-23	25	7
Other operating profits	2	1	2	5	5	2
Other operating costs	0	0	0	0	0	0
EBITDA	-6	-9	-15	-22	27	11
adj. EBITDA	-6	-9	-15	-22	27	11
D&A	0	0	0	0	2	4
EBIT	-6	-10	-16	-23	25	7
Net financial costs	0	0	0	0	0	0
EBT	-4	-9	-14	-18	30	2
Income tax	0	0	0	0	6	0
Minority interest	0	0	0	0	0	0
Net profit	-4	-9	-14	-18	24	2
adj. Net profit	-4	-9	-14	-18	24	2

BalanceSheet(PLNm)	2021	2022	2023	2024E	2025E	2026E
Non-current Assets	2	2	2	5	36	34
Current Assets	7	6	11	38	60	63
Inventories	0	0	0	0	25	25
Receivables	0	0	2	2	2	2
Cash and cash equivalents	6	4	9	9	19	22
Assets	8	8	13	43	96	97
Equity	6	5	10	35	59	61
Minority Interests	0	0	0	0	0	0
Non-current Liabilities	0	0	0	0	0	0
Long-term borrowings	0	0	0	0	0	0
Current Liabilities	2	2	2	8	36	36
Short-term borrowings	0	0	0	0	0	0
Payables	1	1	1	8	12	18
Equity and Liabilities	8	8	13	43	96	97

CashFlowStatement(PLNm)	2021	2022	2023	2024E	2025E	2026E
Cashflow from operating activities	-4	-8	-15	-14	43	6
Changes in working capital	0	1	-1	4	-21	6
D&A	0	0	0	0	2	4
Cashflow from investing activities	0	0	0	-4	-32	-2
CAPEX	0	0	0	-4	-33	-2
Cashflow from financing activities	7	6	20	17	0	0
Dividend / Buy-back	0	0	0	0	0	0
Net change in cash	3	-2	5	-1	11	3
Cash opening balance	3	6	4	9	9	19
Cash closing balance	6	4	9	9	19	22

Valuation

#rNPV

Project	Target Animal Safety (TAS)	Proof of Concept study (PoC)	EMA registration	Market launch	Sales / royalties
BCX-CM-J	Indication- canine osteoarthritis				
phase duration (years)			1	1	
end of phase development	2023	2024	2025	2026	2026
upfront payment & milestone (EURm)			5		24.5%
probability of success (%)*	100%	100%	85%	100%	
cum. probability of success. (%)	100%	100%	85%	85%	
BCX-CM-AD	Indication- canine atopic dermatitis				
phase duration (years)		2	1	1	
end of phase development	2023	2025	2026	2027	2027
upfront payment & milestone (EURm)			10		29.5%
probability of success (%)*	100%	60%	80%	100%	
cum. probability of success. (%)	100%	60%	48%	48%	
BCX-EM	Indication- equine osteoarthritis				
phase duration (years)		1	1	1	
end of phase development	2023	2024	2025	2026	2026
upfront payment & milestone (EURm)			5		29.5%
probability of success (%)*	100%	80%	80%	100%	
cum. probability of success. (%)	100%	80%	64%	64%	

* source: Cancer Drugs Are The Least Likely to Receive FDA Approval, www.fortune.com, 2016; Wong Chi et al. 2019. Estimation of clinical trial success rates and related parameters. *Biostatistics* (20); 2; 273–286

	Valuation			Valuation (PLNm)			Valuation (%)		
	mPLN	PLN/share	% of valuation	Deal value	Royalties	TV	Deal value	Royalties	TV
Clinical pipeline									
BCX-CM-J	269.0	64.9	56%	23.2	225.9	19.9	5%	47%	4%
BCX-CM-AD	139.4	33.6	29%	21.7	109.6	8.1	5%	23%	2%
BCX-EM	70.5	17.0	15%	16.0	49.9	4.6	3%	10%	1%
R&D pipeline valuation	479	116	100%	61	385	33	13%	80%	7%
R&D, SG&A, new lab costs 2024-2026	-103.4								
Net cash 2Q24F	20.0								
BCX valuation (1/1/2024)	396	95.5							
BCX TP 12M: 129 PLN / share									

Risk factors:

1. Risk of failure of new therapy development. Novel drug /therapy development process is associated with a high level of risk of failure. This further increased with the development of new-in-class drugs / novel therapies, whose mechanisms of action focus on novel molecular targets or new therapeutic scheme of treatment. Due to the plan for the commercialization of BCX's projects at the advanced stage of market registration, the great risk of clinical development and registration is held by Bioceltix. We estimate the cumulative probability of clinical success from 16 to 50% depending on the project's therapeutic indication. Up to 2026, Bioceltix plans to spend EUR 4.2m for R&D development, that imposes a level of financial risk assigned to Company's pipeline. We do not exclude partnering conclusion on earlier stages, however, the risk projects failure before reaching the final stage of commercialization of the projects developed cannot be excluded.

2. Risk of MSC-based therapy registration. Stem cells fall between existing legal classifications, being a biological product without a distinct immunologic mechanism and without clear chemical/pharmaceutical characteristics. To a large extent, the novel product development takes place in a foggy environment, where guidance and advice must be patched together from different sources. It is self-evident that for new innovations, the regulators do not have the expertise and cannot issue strong guidance. In the EMA, the CVMP's Ad Hoc Expert Group on Veterinary Novel Therapies (the ADVENT group) has developed Q&A documents with partial pieces of advice. Four problem statements related to stem cells were published for consultation in 2016, asking for input from experts, and three corresponding Q&As were published in 2017; Stem cell Sterility, Extraneous agents and Tumorigenicity. Specific questions on target animal safety in relation to stem cell products are under finalisation. Several of stem-cells based therapies met negative regulatory feedback from FDA or EMA (i.e. Horse Allo 20 in 2018). For this reason, a greater registration risk cannot be ruled out for cellular products vs. standard drugs.

3. The risk of delays in new drug development projects. The development of innovative project is a complex research task which, apart from the elements of drug substance design, also requires a lot of basic research to characterize the molecular target and biological pathways affected. The development of a therapy for which there are no comparable compounds operating on the global pharmaceutical market may involve a longer process of optimizing the pharmacological form, the production process and the planning and implementation of clinical trials in relation to well-known medicinal substances. For this reason, delays in the clinical phases cannot be excluded.

4. Risk of increased competition. The company competes with its programs with other players present on the veterinary market. Therapies developed by the Bioceltix represents novel forms of therapies, which translates into minimizing the risk associated with earlier registration of drugs with an identical form or mechanism of action. However, in the selected therapeutic areas, Bioceltix may face the significant competition from current market players (Zoetis, Boehringer Ingelheim, Elanco, Aratana, Nexvet). The potential market competition could also consist of companies developing other types of drugs for the same diseases, that potentially may result in smaller market shares of Bioceltix projects after the drug market launch.

5. Risk of subsidy return. In 2023, Bioceltix obtained financial support in the form of funds from the European Funds for Modern Economy (FENG) program for development path for a product for Atopic Dermatitis in dogs, including the costs associated with conducting a clinical trial. The total value of eligible expenses in the project is over PLN 17.5m, of which the requested co-financing value is over PLN 10.5m. In the situation of failure to meet the requirements contained in the grant agreement, there may be a risk of ordering the return of part or all of the grant with interest. Possible ordering to return all or part of the granted subsidy may result in the loss of funds, in the worst case - preventing the development of further R&D projects. So far, in the history of the Company's operations, there has been no need to return the significant grant's funds.

6. The risk of falling biotechnology partnering trends. At 2021, on the global pharma market the trend of high volume of partnering transactions had visibly slowed down. The macroeconomic and geopolitical environment may again result of a tendency of R&D expenditures reduction of global pharmaceutical concerns and the availability of financing in the form of partnering agreements may be reduced. Consequently, such risk may translate into a decline in interest in the Bioceltix projects.

7. Risk related to the loss of scientific staff. The company's operations depend on the employment of qualified scientific and managerial staff with the necessary qualifications and experience in the development of MSC-based therapies. The loss of specialist staff and key managers may adversely affect research opportunities and clinical projects implemented. Thus, there is a risk that the Company will not be able to retain the current staff or recruit new employees, or will be forced to increase staff costs in order to bind key staff together. In order to minimize such risk, Bioceltix introduced an Incentive Program for managers and employees.

8. Currency risk. The company incurs research costs in Poland and abroad, and therefore incurs expenses denominated in PLN as well as in foreign currencies. In particular, the Company settles accounts with certain service providers providing the Company with services related to research in foreign currencies. Bioceltix also plans to sell its therapies in EU market- a great part of the revenues and costs will be subjected to denomination from foreign currencies, mostly EUR. Hence, it cannot be ruled out that in the event of an unfavourable PLN / EUR or PLN / USD exchange might negatively affect the company's cashflows.

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**NAGRŃDY
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2023

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Glossary of professional terms:

capitalisation – market price multiplied by the number of a company's shares
 free float (%) – percentage of a company's shares held by shareholders with less than 5% of total voting rights attached to the shares, reduced by treasury shares held by the company
 min/max 52 wks – lowest/highest share price over the previous 52 weeks
 average turnover – average volume of share trading over the previous month

EBIT – operating profit
 EBITDA – operating profit before depreciation and amortisation
 adjusted profit – net profit adjusted for one-off items
 CF – cash flow
 CAPEX – sum of investment expenditures on fixed assets
 OCF – cash generated through a company's operating activities
 FCF – cash generated by a company after accounting for cash outflows to support its operations and maintain capital assets
 ROA – rate of return on assets
 ROE – rate of return on equity
 ROIC – rate of return on invested capital
 NWC – net working capital
 cash conversion cycle – length of time it takes for a company to convert its cash investments in production inputs into cash revenue from sale of its products or services
 gross profit margin – ratio of gross profit to net revenue
 EBITDA margin – ratio of the sum of operating profit and depreciation/amortisation to net revenue
 EBIT margin – ratio of operating profit to net revenue
 net margin – ratio of net profit to net revenue
 EPS – earnings per share
 DPS – dividend per share
 P/E – ratio of market price to earnings per share
 P/BV – ratio of market price to book value per share
 EV/EBITDA – ratio of a company's EV to EBITDA
 EV – sum of a company's current capitalisation and net debt
 DY – dividend yield, ratio of dividends paid to share price
 RFR – risk free rate
 WACC – weighted average cost of capital

Recommendations of the Brokerage House

Issuer – Biocellix S.A.
 BUY – we expect the total return on an investment to reach at least 15%
 HOLD – we expect the price of an investment to be largely stable, with potential upside of up to 15%
 SELL – we expect negative total return on an investment of more than -0%

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 Document prepared by: Katarzyna Kosiorek

Valuation methods used

[The Discounted Cash Flow \(DCF\) method values a company by estimating its future cash flows and discounting them back to their present value.](#)

- Advantages: future-oriented, flexible when it comes to assumptions, based on the intrinsic value of a company, widely accepted.
 - Disadvantages: sensitivity to assumptions, complexity, subjectivity, doesn't consider market sentiment or short-term fluctuations.

The comparable valuation method values a company by comparing it to similar publicly traded companies.
 - Advantages: simplicity, transparency, benchmarking, reflects current market valuations and investor sentiment.
 - Disadvantages: lack of specificity, limited comparables, sensitive to market fluctuations, ignoring fundamental differences.

SOTP – sum-of-the-parts method, which consists in valuing a company by valuing its individual business lines separately and then summing them up.
 - Advantages: different valuation methods can be applied to diverse business lines; the approach is useful for assessing the value of a company e.g. in the case of planned acquisition or restructuring.
 - Disadvantages: the peer group for individual business lines is usually limited, the method does not adequately account for synergies between business segments.

Risk-adjusted net present value method (rNPV)
 - Advantages: accounting for probabilities assigned to future cash flows, providing a more realistic assessment of the present value of future cash flows and reflecting business-specific factors, especially in the case of innovative companies.
 - Disadvantages: subjectivity involved in the adoption of a discount rate, significant reliance on a number of assumptions, high level of complexity in the calculations and exclusion of qualitative factors from the valuation.

Discounted residual income method (DRI)
 - Advantages: valuation based on the excess of income over risk-adjusted opportunity cost to owners of capital, the method can be applied to companies that do not pay dividends or generate positive FCF.
 - Disadvantages: significant reliance on subjective judgements and assumptions, as well as sensitivity of the valuation to any changes in those variables.

Discounted dividend model (DDM)
 - Advantages: accounting for real cash flows to equity owners, the model works best for companies with a long history of dividend distribution.
 - Disadvantages: the method can be applied to dividend-paying companies only, it is not suitable for companies with a short history of dividend distribution.

Net asset value method (NAV)
 - Advantages: the approach is particularly relevant to holding companies with significant property, plant and equipment assets, the calculation of NAV is relatively straightforward.
 - Disadvantages: the method neglects future revenue or earnings potential and may not properly reflect the value of intangible assets.

Target multiple method

- Advantages: the method can be applied to any company.
- Disadvantages: it involves a high degree of subjectivity.

Replacement value method – it assesses the value of a company based on the costs of replacing its assets.

- Advantages: the method is particularly relevant to companies with significant property, plant and equipment assets.
- Disadvantages: it may be hard to capture the value of a company's intangible assets, reputation and market potential.

Liquidation value method – the sum of prices that the business would receive upon selling its individual assets on the open market.

- Advantages: the method can capture the lowest threshold of a company's value.
- Disadvantages: it may be hard to capture the value of a company's intangibles.

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