Research

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Bioceltix

Closer to EMA registration

Buy

Recent: Buy

Target price: 133 PLN
upside potential: +61%

In recent months, Bioceltix has achieved significant milestones in its R&D projects. In the BCX-CM-J project, dedicated to the treatment of osteoarthritis in dogs, the company is successfully advancing its marketing authorization application with the EMA—so far, the regulator has not raised any objections that could negatively impact the continuation of the registration process. Bioceltix has also published information about a pilot study on the treatment of atopic dermatitis in dogs. The results confirmed the high therapeutic potential of BCX-CM-AD, demonstrating stronger and faster anti-inflammatory effects compared to current standards of care, which enabled a reduction in the initial number of patients recruited for the clinical trial by approximately 30%.Bioceltix also presented the final results of clinical trials for BCX-EM, a therapy for osteoarthritis in horses, confirming the project's efficacy and safety. These achievements have increased the probability of success for the mentioned projects. We propose that Bioceltix has the potential for significant regulatory and clinical updates ahead—we anticipate that further key commercialization steps may occur as the EMA registration process progresses in the first half of 2025. In our view, a favorable distribution agreement strategy involving a lower upfront payment and high double-digit royalty rates could provide a more profitable long-term revenue stream compared to a commercialization transaction with a full IP sale. Considering the prospects of continuing the EMA registration process and the option for initial licensing agreements, we maintain our "Buy" recommendation for Bioceltix, with a 12-month target share price of PLN 133.0 (+56% upside).

3 projects at pre-regulatory and clinical stage. The current portfolio of BCX's projects includes 3 projects at the clinical stage of development and early phase projects with more biological drugs for companion animals. The active substance of the therapies contain a suspension of live allogeneic mesenchymal stem cells derived from adipose tissue. **BCX-CM-J** represents a somatic cell therapy product in the form of a suspension of live allogeneic mesenchymal stem cells intended for intra-articular injections to treat osteoarthritis, manifested by pain and lameness of the animal. **BCX-CM-J** represents second project in BCX pipeline is veterinary biological drug based on stem cells, intend to treat canine atopic dermatitis**. BCX-EM** contains mesenchymal stem cells used in parenteral injections to treat equine osteoarthritis therapy, caused by inflammation of the joints, resulting from excessive strain on the locomotor system. So far, BCX's projects are the only treatment worldwide based on adipose MSC cells in the veterinary use.

Project Status. 1) BCX-CM-J (Osteoarthritis Therapy for Dogs): A marketing authorization application was submitted to EMA in May 2024. By July 2024, EMA confirmed the application met criteria for substantive evaluation. In August 2024, BCX received an extension of GMP certification for commercial-scale manufacturing. Feedback from EMA in November 2024 indicated no significant risks beyond standard market authorization risks. **2) BCX-CM-AD (Atopic Dermatitis Therapy for Dogs):** Currently in clinical trials. Intermediate analysis conducted in July 2024 refined the total patient count from an estimated 120 to 84 participants. **3) BCX-EM (Osteoarthritis Therapy for Horses):** In a pivotal clinical development phase. Final readings in December 2024 confirmed the therapy's effectiveness. Clinical trials included 117 patients, with 78 receiving BCX-EM and 39 receiving a placebo. Results showed 71.1% of the treatment group experienced moderate, significant, or complete symptom relief by day 845, compared to 18.4% in the placebo group.

First partnerships planned for 2025. BCX is in discussions with potential market partners, and several large entities have already conducted technical due diligence. Significant revenues are expected with the market introduction of BCX-CM-J in the second half of 2025. A distribution agreement could be finalized by the first half of 2025, with an upfront payment of EUR 5-10 million anticipated.

Plans of growing production capacity. By 2025, production capacity is expected to reach 10,000 doses per year. Construction of a new production facility in Wrocław, Poland, is on schedule. The facility will house six cell cultivation incubators, initially tripling current production capacity. The building is expected to be handed over in Q1 2025, followed by nine months of installation work. Additional equipment and incubation modules will enable further capacity increases.

Bioceltix key R&D newsflow: Trigon assumptions. 1) BCX-CM-J: Distribution agreement: 1Q25, Market authorization: End of 1H25**; 2) BCX-CM-AD:** Completion of patient observation in clinical trials: 4Q24/1Q25, Publication of trial results: 1Q25 Submission of EMA registration dossier: 1H25**; 3) BCX-EM:** Submission of EMA registration dossier: 1Q25

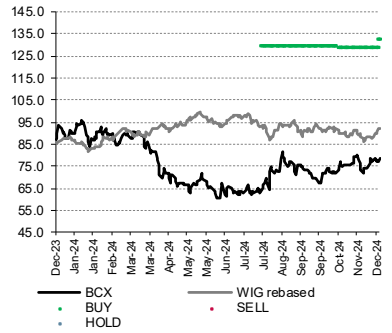
Valuation. The 12-month target share price for Bioceltix is estimated at PLN 133.0 (+56% upside), based on a Sum-of-the-Parts (SOTP) valuation using the rNPV method. Success probability for BCX-CM-J clinical trials increased from 85% to 90%, and for BCX-EM from 80% to 85%, compared to prior projections.

Risk factors. Key risks include: 1) Development failures; 2) Delays in project milestones; 3) Regulatory and commercialization risks (e.g., absence of partnerships, lower-than-expected market sales); 4) Changes in clinical success rates, market shares, royalties, or extended clinical phases; 5) Rising market competition. For detailed analysis, refer to page 8 of the report.

FACT SHEET

Ticker			BCX
Sector			Biotech & MedTech
Price (PLN)			85.3
52wk Range (PLN)			59 / 98
Number of share (m)			4.9
Market Cap (mPLN)			420
Free-float			60%
Avg Vol 3M (mPLN)			0.3
Price performance	**1M**	**3M**	**1Y**
	4.5%	3.7%	23.6%

RELATIVE SHARE PRICE PERFORMANCE



RECOMMENDATION HISTORY	Date	Price
Buy	05.12.2024	133
Buy	20.10.2024	129
Buy	29.07.2024	130

SHAREHOLDERS	Share %
Kvarko Group ASI	9.6%
PZU TFI	9.3%
Total FIZ	8.3%
Łukasz Bzdzion	7.4%
Alternative Solution ASI SA	5.2%
Other shareholders	60.2%

IMPORTAND DATES

ANALYST

Katarzyna Kosiorek

VALUATION

GENERAL ASSUMPTIONS

1) The presented valuation of the Bioceltix is based on the rNPV method (risk-adjusted net present value), which is the basic method used for valuation of biotech / medtech companies in the initial development phase. This method modifies the DCF valuation by adjusting for the likelihood that a molecule / therapy will successfully move to the next trial phase, ultimately proceed to registration;

2) We have adopted the 2024–2039 forecast period. We assume that for the most significant part for the forecasts period, BCX projects would not be subject to patent protection. The company has adopted a strategy of no patenting key manufacturing processes in order not to disclose the "state of the art". The manufacturing process for stem cell-based therapies is a highly complex technique, characterized by a high barrier to entry into a selected technology. For this reason, in the forecast period we assumed that Bioceltix may be exposed to the situation of negative competition impact in the area of cell therapies, as well as other competitive solutions in selected therapeutic areas. For this reason we applied the assumption of negative competition impact, reducing the target patient market and putting pressure on the cost of therapy (an effect of about 30% reduction in the above aspects). We applied this effect in the forecast period from 2031.

3) The final valuation is the sum of the partial valuations (SOTP) of R&D projects for specified therapeutic indications: **1)** BCX-CM-J in canine osteoarthrosis; **2)** BCX-CM-AD in canine atopic dermatitis and **3)** BCX-EM in horse osteoarthritis therapy.

4) There is a limited information on clinical success rates in veterinary indications. Therefore, we applied the likelihoods of success are based on the data published in the scientific literature concerning human trials (Wong Chi et al. 2019. *Estimation of clinical trial success rates and related parameters*. Biostatics (20); 2; 273–286) and in industry reports (Cancer Drugs Are The Least Likely to Receive FDA Approval, www.fortune.com, May 2016 (clinical development). In our opinion, this approach translates into more sophisticated and secure valuation assumptions. Any regulatory facilitation (EMA, FDA) in the field of veterinary therapies will mean a valuable upside for the valuation of BCX projects.

5) For the BCX projects, we assume partnering agreements to be signed at the stage of finished clinical trials before the market registration of the project in the EU. In our assumptions, we do not include the possible registration and sales on the US market due to lack of advanced stage of regulatory process. From the moment of signing the partnering, we assume that the partner takes over the sales development of the projects. BCX will be responsible for therapeutic dosages production (due to the complexity of the technological process) and will be eligible to receiving royalties from market sales of the drugs.

6) We assume total costs regarding clinical trials and new production plant development until the end of 2026 at EUR 16m. In our valuation assumptions further R&D work and production capacity expansion will be financed from BCX secured sources: **1)** own resources (PLN 7m, at the end of 1Q24) and **2)** PARP grant financing for BCX-CM-AD (PLN 10.6m with the execution time for 2026), and **3)** SPO sources (PLN 44m), that should secure operational financing until the end of 2026.

7) In potential BCX's therapies sales forecast, we use own assumptions regarding targeted patient's population. This assumption was based on statistical data regarding number of dogs and horses in the EU, as well as scientific market reports regarding prevalence on osteoarthritis, atopic dermatitis and equine osteoarthritis therapy. The potential single dose therapy cost was based on the competitive therapies' costs with the technological complexity of the production process (obtaining source material, therapeutic dosages). The cost of dosage production was adopted from own assumptions regarding other cell therapies production processes. The market penetration of BCX's therapies was based on historical levels of market sales of newly registered drugs in veterinary and stem cells

therapies (see financial assumptions section).

8) We assume parameters of partnering agreements (upfront payment) at the level of 5-10% of the median of total values of comparable transactions in veterinary transaction (discount to comparable transactions). Analysed transactions regarding veterinary therapies were mostly M&A processes- we assume that in the possible deal of BCX and partners transaction construction may differ due to production element that would stay on BCX business. Therefore, we assume small upfront payment (EUR 5-10m in the moment of transaction conclusion and significant double-digit level of royalty rates (20-25%);

9) EUR/PLN exchange rate 4.3; USD/EUR for the purpose of determining the market size adopted at 0.93;

10) Risk premium specific for research projects has been included in the likelihood of finishing the different phases of clinical trial and reflected in FCF calculation. Weighted average cost of capital of the Company (discount rate) has been assumed at 17% (assumption based on the analysis of the companies from biotech sector, New York Stern Database 2024);

11) Effective tax rate at 19%.

Valuation. The 12-month target share price for Bioceltix is estimated at PLN 133.0 (+56% upside), based on a Sum-of-the-Parts (SOTP) valuation using the rNPV method. Success probability for BCX-CM-J clinical trials increased from 85% to 90%, and for BCX-EM from 80% to 85%, compared to prior projections. .

BCX: company valuation.

	Valuation			Valuation (PLNm)			Valuation (%)		
	mPLN	PLN/share	% of valuation	Deal value	Royalties	TV	Deal value	Royalties	TV
Clinical pipeline									
BCX-CM-J	271.8	65.6	57%	24.6	227.2	20.0	5%	48%	4%
BCX-CM-AD	133.5	32.2	28%	21.7	104.1	7.7	5%	22%	2%
BCX-EM	72.1	17.4	15%	17.0	50.5	4.6	4%	11%	1%
R&D pipeline valuation	**477**	**115**	**100%**	**63**	**382**	**32**	**13%**	**80%**	**7%**
R&D, SG&A, new lab costs 2024-2026	-118.6								
Net cash 2Q24F	38.2								
BCX valuation (1/1/2024)	**397**	**95.8**							
BCX TP 12M: 133 PLN / share									

Source: Trigon

BCX: Trigon valuation assumptions summary

Project	Target Animal Safety (TAS)	Proof of Concept study (PoC)	EMA registration	Market launch	Sales / royalties
BCX-CM-J	**Indication- canine osteoarthrosis**				
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%	90%	95%	
cum. probability of success. (%)	100%	100%	90%	86%	
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%	95%	
cum. probability of success. (%)	100%	60%	48%	46%	
BCX-EM	**Indication- equine osteoarthrosis**				
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%	85%	95%	
cum. probability of success. (%)	100%	80%	68%	65%	

** 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. Biostatics (20); 2; 273–286*

Source: Trigon

COSTS ASSUMPTIONS

Until end of 2026, we assume that Bioceltix will invest approx. PLN 80-85m. We take into account the company's assumptions regarding the allocation of approx. PLN 12-15m for R&D works, however, from the point of view of the safety of forecasts, we assume that the above budget may increase additionally by PLN 2-3m due to the growing inflationary pressure. We assume approx. c.a. PLN 6-7m for the clinical development of the BCX-CM-AD project in the area of canine atopic dermatitis; ca. PLN 4-5m for BCX-EM in horse osteoarthritis therapy and PLN 2-3m for other early R&D projects development. In our costs assumption, we also include cash sources essential for new production plant preparation (we PLN 35-40m) and SG&A costs (PLN 25-30m).

BCX: Trigon's assumptions regarding cash expenses in 2024-2026.

PLNm	2024	2025	2026
R&D costs	11.3	1.3	0.6
SG&A	7.7	7.7	10.3
New production site	3.9	32.5	2.0

Source: Trigon

BCX-CM-J PROJECT VALUATION

1) **Primary therapeutic area:** canine osteoarthrosis

2) **Current project status:** Pivotal study completed

3) **Number of dogs in EU in 2023:** 105.4m (*source: statista.com)*

4) **Disease prevalence 2023:** 20-25% of all dog population (*source: caninearthritis.co.uk/ what-is-arthritis,* 2024*)*

5) **CAGR 2024-2030 (%) of the disease market**: 4.8% (source: GMinsights report 2024)

6) **Market share**: a 3.0% market share (own assumption)

7) **Duration and likelihood of proceeding to subsequent phases of clinical trial:** based on Wong Chi et al. 2019. Estimation of clinical trial success rates and related parameters. Biostatics (20); 2; 273–286

Project valuation:

BCX-CM-J	2024F	2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
milestone (EURm)	0.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
patients number (m)	0.632	0.663	0.695	0.728	0.763	0.799	0.838	0.865	0.892	0.921	0.950	0.981	1.012	1.045	1.078	1.112
prevalence dynamics (y/y)	4.8%	4.8%	4.8%	4.8%	4.8%	4.8%	4.8%	3.2%	3.2%	3.2%	3.2%	3.2%	3.2%	3.2%	3.2%	3.2%
annual dosage per patient	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
dosage price (EUR)	270.0	270.0	270.0	270.0	270.0	270.0	270.0	180.0	180.0	180.0	180.0	180.0	180.0	180.0	180.0	180.0
BCX production capacity (m / year)	0.00	0.02	0.03	0.05	0.10	0.20	0.40	0.60	0.80	1.00	1.20	1.40	1.60	1.80	1.80	1.80
Total sales (EURm)	0	5	13	20	41	86	181	187	257	332	411	494	583	677	699	721
Single dosage production cost (EUR)	20.0	20.0	20.0	20.0	20.0	20.0	20.0	26.7	26.7	26.7	26.7	26.7	26.7	26.7	26.7	26.7
Production costs / year (EURm)	0.0	0.3	0.7	1.0	2.0	4.0	8.0	16.0	21.3	26.7	32.0	37.3	42.7	48.0	48.0	48.0
Net revenues (EURm)	**0.0**	**3.8**	**8.5**	**12.5**	**25.0**	**50.0**	**100.0**	**92.0**	**122.7**	**153.3**	**184.0**	**214.7**	**245.3**	**276.0**	**276.0**	**276.0**
BCX royalties (%)	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%	24.5%
BCX net revenues (EURm)	**0.0**	**5.9**	**2.1**	**3.1**	**6.1**	**12.3**	**24.5**	**22.5**	**30.1**	**37.6**	**45.1**	**52.6**	**60.1**	**67.6**	**67.6**	**67.6**
probability	100%	90%	86%	86%	86%	86%	86%	86%	86%	86%	86%	86%	86%	86%	86%	86%
milestone	0.0	4.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Royalties (EURm)	0.0	5.3	1.8	2.6	5.2	10.5	20.9	19.3	25.7	32.1	38.5	45.0	51.4	57.8	57.8	57.8
Total revenues probability adj. (EURm)	0.0	9.8	1.8	2.6	5.2	10.5	20.9	19.3	25.7	32.1	38.5	45.0	51.4	57.8	57.8	57.8
Total revenues (PLNm)	0.0	42.3	7.7	11.3	22.5	45.0	90.1	82.9	110.5	138.1	165.7	193.4	221.0	248.6	248.6	248.6
TOTAL (PLNm)	**0.0**	**42.3**	**7.7**	**11.3**	**22.5**	**45.0**	**90.1**	**82.9**	**110.5**	**138.1**	**165.7**	**193.4**	**221.0**	**248.6**	**248.6**	**248.6**
Tax	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%
FCF (PLNm)	0.0	34.2	6.2	9.1	18.2	36.5	73.0	67.1	89.5	111.9	134.2	156.6	179.0	201.4	201.4	201.4
discount rate	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%
discount factor	0.85	0.72	0.61	0.52	0.44	0.37	0.31	0.27	0.23	0.19	0.16	0.14	0.12	0.10	0.08	0.07
DFCF	0.0	24.6	3.8	4.7	8.0	13.5	22.9	17.9	20.2	21.4	21.7	21.5	20.8	19.8	16.8	14.3
DFCF sum (mln PLN)	**251.8**															
growth rate in TV	-10%															
Residual value (TV)	647.3															
Present TV	**20.0**															
Valuation (PLNm)	**271.8**															

Source: Trigon

BCX-CM-AD PROJECT VALUATION

1) **Primary therapeutic area:** canine atopic dermatitis

2) **Current project status:** Pivotal study launched

3) **Number of dogs in EU in 2023:** 105.4m (*source: statista.com)*

4) **Disease prevalence 2023:** 15-20% of all dog population (*source: www.ncbi.nlm.nih.gov/pmc/articles/PMC10874193/*

5) **CAGR 2024-2030 (%) of the disease market**: 4.5% (source: CoherentMarketInsights report 2024)

6) **Market share**: a 2.5% market share (own assumption)

7) **Duration and likelihood of proceeding to subsequent phases of clinical trial:** based on Wong Chi et al. 2019. Estimation of clinical trial success rates and related parameters. Biostatics (20); 2; 273–286

Project valuation:

BCX-CM-AD	2024F	2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
milestone (EURm)	0.0	0.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
patients number (m)	0.395	0.413	0.432	0.451	0.471	0.493	0.515	0.530	0.546	0.562	0.579	0.597	0.615	0.633	0.652	0.672
prevalence dynamics (y/y)	4.5%	4.5%	4.5%	4.5%	4.5%	4.5%	4.5%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
annual dosage per patient	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
dosage price (EUR)	540.0	540.0	540.0	540.0	540.0	540.0	540.0	360.0	360.0	360.0	360.0	360.0	360.0	360.0	360.0	360.0
BCX production capacity (m / year)	0.00	0.00	0.01	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50	0.55	0.60	0.65
Total sales (EURm)	0	0	5	27	54	81	108	90	108	126	144	162	180	198	216	234
Single dosage production cost (EUR)	80.0	80.0	80.0	80.0	80.0	80.0	80.0	106.7	106.7	106.7	106.7	106.7	106.7	106.7	106.7	106.7
Production costs / year (EURm)	0.0	0.0	0.8	4.0	8.0	12.0	16.0	26.7	32.0	37.3	42.7	48.0	53.3	58.7	64.0	69.3
Net revenues (EURm)	**0.0**	**0.0**	**4.6**	**23.0**	**46.0**	**69.0**	**92.0**	**63.3**	**76.0**	**88.7**	**101.3**	**114.0**	**126.7**	**139.3**	**152.0**	**164.7**
BCX royalties (%)	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%
BCX net revenues (EURm)	**0.0**	**0.0**	**11.4**	**6.8**	**13.6**	**20.4**	**27.1**	**18.7**	**22.4**	**26.2**	**29.9**	**33.6**	**37.4**	**41.1**	**44.8**	**48.6**
probability	60%	60%	48%	46%	46%	46%	46%	46%	46%	46%	46%	46%	46%	46%	46%	46%
milestone	0.0	0.0	4.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Royalties (EURm)	0.0	0.0	5.5	3.1	6.2	9.3	12.4	8.5	10.2	11.9	13.6	15.3	17.0	18.7	20.4	22.2
Total revenues probability adj. (EURm)	0.0	0.0	10.3	3.1	6.2	9.3	12.4	8.5	10.2	11.9	13.6	15.3	17.0	18.7	20.4	22.2
Total revenues (PLNm)	0.0	0.0	44.1	13.3	26.6	39.9	53.2	36.6	44.0	51.3	58.6	65.9	73.3	80.6	87.9	95.2
TOTAL (PLNm)	**0.0**	**0.0**	**44.1**	**13.3**	**26.6**	**39.9**	**53.2**	**36.6**	**44.0**	**51.3**	**58.6**	**65.9**	**73.3**	**80.6**	**87.9**	**95.2**
Tax	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%
FCF (PLNm)	0.0	0.0	35.7	10.8	21.6	32.3	43.1	29.7	35.6	41.5	47.5	53.4	59.3	65.3	71.2	77.2
discount rate	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%
discount factor	0.85	0.72	0.61	0.52	0.44	0.37	0.31	0.27	0.23	0.19	0.16	0.14	0.12	0.10	0.08	0.07
DFCF	0.0	0.0	21.7	5.6	9.4	12.0	13.5	7.9	8.0	7.9	7.7	7.3	6.9	6.4	5.9	5.5
DFCF sum (mln PLN)	**125.8**															
growth rate in TV	-10%															
Residual value (TV)	248.0															
Present TV	**7.7**															
Valuation (PLNm)	**133.5**															

Source: Trigon

BCX-EM PROJECT VALUATION

1) **Primary therapeutic area:** equine osteoarthrosis

2) **Current project status:** Pivotal study ongoing (patients recruitment ended)

3) **Number of horses in EU in 2023 :** 7.1m (*source: eurogroupforanimals.org)*

4) **Disease prevalence 2023:** 25% of all horse population (*source: https:// www.ncbi.nlm.nih.gov/pmc/articles/PMC9197312/*

5) **CAGR 2024-2030 (%) of the disease market**: 3.9% (source: https://www.linkedin.com/ pulse/global-horse-racing-market-report-size-growth-cagr-around-howard/)

6) **Market share**: a 4.0% market share (own assumption)

7) **Duration and likelihood of proceeding to subsequent phases of clinical trial:** based on Wong Chi et al. 2019. Estimation of clinical trial success rates and related parameters. Biostatics (20); 2; 273–286

Project valuation:

BCX-EM	2024F	2025F	2026F	2027F	2028F	2029F	2030F	2031F	2032F	2033F	2034F	2035F	2036F	2037F	2038F	2039F
milestone (EURm)	0.0	5.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
patients number (m)	1.775	1.844	1.916	1.991	2.069	2.150	2.234	2.292	2.351	2.413	2.475	2.540	2.606	2.674	2.744	2.815
prevalence dynamics (y/y)	3.9%	3.9%	3.9%	3.9%	3.9%	3.9%	3.9%	2.6%	2.6%	2.6%	2.6%	2.6%	2.6%	2.6%	2.6%	2.6%
annual dosage per patient	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
dosage price (EUR)	900.0	900.0	900.0	900.0	900.0	900.0	900.0	600.0	600.0	600.0	600.0	600.0	600.0	600.0	600.0	600.0
BCX production capacity (m / year)	0.00	0.00	0.00	0.01	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.10	0.11	0.12
Total sales (EURm)	0	0	1	5	9	18	27	24	30	36	42	48	54	60	66	72
Single dosage production cost (EUR)	15.0	15.0	15.0	15.0	15.0	15.0	15.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Production costs / year (EURm)	0.0	0.0	0.0	0.1	0.2	0.3	0.5	0.8	1.0	1.2	1.4	1.6	1.8	2.0	2.2	2.4
Net revenues (EURm)	**0.0**	**0.0**	**0.9**	**4.4**	**8.9**	**17.7**	**26.6**	**23.2**	**29.0**	**34.8**	**40.6**	**46.4**	**52.2**	**58.0**	**63.8**	**69.6**
BCX royalties (%)	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%	29.5%
BCX net revenues (EURm)	**0.0**	**5.0**	**0.3**	**1.3**	**2.6**	**5.2**	**7.8**	**6.8**	**8.6**	**10.3**	**12.0**	**13.7**	**15.4**	**17.1**	**18.8**	**20.5**
probability	80%	68%	65%	68%	65%	65%	65%	65%	65%	65%	65%	65%	65%	65%	65%	65%
milestone	0.0	3.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Royalties (EURm)	0.0	3.4	0.2	0.9	1.7	3.4	5.1	4.4	5.5	6.6	7.7	8.8	9.9	11.1	12.2	13.3
Total revenues probability adj. (EURm)	0.0	6.8	0.2	0.9	1.7	3.4	5.1	4.4	5.5	6.6	7.7	8.8	9.9	11.1	12.2	13.3
Total revenues (PLNm)	0.0	29.2	0.7	3.8	7.3	14.5	21.8	19.0	23.8	28.5	33.3	38.0	42.8	47.5	52.3	57.0
TOTAL (PLNm)	**0.0**	**29.2**	**0.7**	**3.8**	**7.3**	**14.5**	**21.8**	**19.0**	**23.8**	**28.5**	**33.3**	**38.0**	**42.8**	**47.5**	**52.3**	**57.0**
Tax	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%
FCF (PLNm)	0.0	23.7	0.6	3.1	5.9	11.7	17.6	15.4	19.2	23.1	26.9	30.8	34.6	38.5	42.3	46.2
discount rate	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%	18.0%
discount factor	0.85	0.72	0.61	0.52	0.44	0.37	0.31	0.27	0.23	0.19	0.16	0.14	0.12	0.10	0.08	0.07
DFCF	0.0	17.0	0.4	1.6	2.6	4.4	5.5	4.1	4.3	4.4	4.4	4.2	4.0	3.8	3.5	3.3
DFCF sum (mln PLN)	**67.5**															
growth rate in TV	-10%															
Residual value (TV)	148.5															
Present TV	**4.6**															
Valuation (PLNm)	**72.1**															

Source: Trigon

Risk factors

Among the main risk factors for the valuation of Bioceltix, we identify elements directly related to the development of innovative therapies, i.e. the risk of project development failure, time delays in completing individual stages of development, regulatory and commercialisation risks (no partnering contracts, risks of lower market sales of the products). We also distinguished several risks concerning the main assumptions to our valuation like changes in clinical success rates, market shares, royalties rates and clinical phases duration extensions (see Valuation sensitivity section). Among the other factors, we identify risks related to increased competition, grant aspects, loss of academic staff, legal risks related to the ownership of IP rights and macroeconomic risks.

Risk of failure of new drug development projects. 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. Depending on the therapeutic area, the cumulative probability of passing Phase 1 clinical trials to drug registration is 5% to 12%, except for rare diseases indications for which the probability is 25% (Nature Drugs Review 2020, Fortune 2016). 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, Biceltix 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.

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.

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.

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 consists 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.

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.

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. Past Covid-19 spike in interest to global biotech assets, investor appetite to invest into biotechs via issues has also declined, as has the value of the sector overall, with small cap firms bearing taking biggest hit. However, the current both Big Pharma and investors sentiment has change and a positive effect on the number of partnering deals is observable. 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.

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 (see "Company section").

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.

Financial forecasts

Income statement (PLNm)

	2021	2022	2023	2024F	2025F	2026F
Revenues	**0.0**	**0.0**	**0.0**	**0.0**	**35.8**	**17.7**
Revenues from MSC-based therapies	0.0	0.0	0.0	0.0	35.8	17.7
Operating costs	6.2	9.7	15.8	20.8	10.3	10.7
COGS	0.0	0.0	0.0	0.0	1.3	6.4
Profit from sales	**-6.2**	**-9.7**	**-15.8**	**-20.8**	**25.4**	**7.0**
Other operating profits	1.9	0.8	1.8	3.3	5.0	2.0
Other operating costs	0.0	0.1	0.0	0.0	0.0	0.0
EBITDA	**-5.8**	**-9.2**	**-15.4**	**-20.3**	**26.8**	**10.8**
adj. EBITDA	**-5.8**	**-9.2**	**-15.4**	**-20.3**	**26.8**	**10.8**
D&A	0.4	0.4	0.4	0.5	1.3	3.8
EBIT	**-6.2**	**-9.7**	**-15.8**	**-20.8**	**25.4**	**7.0**
Net financial costs	0.0	0.1	0.4	0.6	0.9	0.9
EBT	**-4.4**	**-9.6**	**-15.4**	**-20.3**	**26.3**	**2.4**
Income tax	0.0	0.0	0.0	0.1	5.8	0.4
Minority interest	0.0	0.0	0.0	0.0	0.0	0.0
Net profit	**-4.4**	**-8.9**	**-15.4**	**-20.1**	**32.1**	**1.9**
adj. Net profit	**-4.4**	**-8.9**	**-13.7**	**-17.6**	**24.7**	**1.9**
sales margin	-	-	-	-	71.1%	39.7%
EBITDA adj. margin	-	-	-	-	74.9%	61.3%
EBIT margin	-	-	-	-	71.1%	39.7%
net profit adj. margin	-	-	-	-	69.2%	10.8%
sales growth y/y	-	-	-	-	-	-50.6%
prfit on sales growth y/y	425.0%	236.4%	-77.3%	-40.0%	-	-
EBITDA adj. growth y/y	-	-	-	-	-	-59.6%
EBIT growth y/y	-	-	-	-	-	-72.5%
net profit adj. growth y/y	-	-	-	-	-	-92.3%

Source: Bioceltix-historical data, Trigon - forecasts

	3Q23	4Q23	1Q24	2Q24	3Q24	4Q24F
Revenues	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Revenues from MSC-based therapies	0.0	0.0	0.0	0.0	0.0	0.0
Operating costs	4.0	5.1	4.6	5.5	4.1	6.7
COGS	-4.0	-5.1	-4.6	-5.5	-4.1	-6.7
Profit from sales	**-4.0**	**-5.1**	**-4.6**	**-5.5**	**-4.1**	**-6.7**
Other operating profits	0.4	1.1	0.4	1.3	0.6	1.0
Other operating costs	0.0	0.0	0.0	0.0	0.0	0.0
EBITDA	**-3.6**	**-3.8**	**-4.1**	**-4.0**	**-3.3**	**-5.5**
adj. EBITDA	**-3.9**	**-5.0**	**-4.5**	**-5.4**	**-3.9**	**-6.5**
D&A	0.1	0.1	0.1	0.1	0.1	0.2
EBIT	**-3.7**	**-4.0**	**-4.2**	**-4.2**	**-3.5**	**-5.7**
Net financial costs	0.1	0.1	0.0	-0.1	0.0	0.0
EBT	**-3.5**	**-3.8**	**-4.2**	**-4.2**	**-3.4**	**-5.7**
Income tax	0.0	0.0	0.0	0.0	0.0	0.1
Minority interest	0.0	0.0	0.0	0.0	0.0	0.0
Net profit	**-3.5**	**-3.8**	**-4.2**	**-4.2**	**-3.5**	**-5.7**
adj. Net profit	**-3.8**	**-4.9**	**-4.6**	**-5.5**	**-4.1**	**-6.7**
gross margin	-	-	-	-	-	-
EBITDA adj. margin	-	-	-	-	-	-
EBIT margin	-	-	-	-	-	-
net profit adj. margin	-	-	-	-	-	-
sales growth y/y	-	-	-	-	-	-
gross profit growth y/y	-86.4%	39.6%	-28.6%	-4.9%	-29.2%	-
EBITDA adj. growth y/y	-	-	-	-	-	-
EBIT growth y/y	-	-	-	-	-	-
net profit adj. growth y/y	-	-	-	-	-	-

Source: Bioceltix-historical data, Trigon - forecasts

Balance sheet (PLN m)

	2021	2022	2023	2024F	2025F	2026F
Fixed assets	**1.7**	**1.6**	**1.5**	**2.6**	**33.7**	**31.9**
Tangible fixed assets	1.5	1.5	1.5	2.1	33.3	31.5
Intangible assets	0.0	0.0	0.0	0.0	0.0	0.0
Company's value	0.0	0.0	0.0	0.0	0.0	0.0
Long-term receivables	0.1	0.1	0.0	0.4	0.4	0.4
Long-term investments	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0	0.0
Current assets	**6.5**	**6.0**	**11.2**	**36.3**	**55.7**	**54.8**
Inventory	0.0	0.0	0.0	0.0	25.0	24.7
Trade receivables	0.4	0.2	1.9	2.0	2.1	2.2
Other	0.0	1.7	0.0	0.1	0.0	0.0
Cash	6.1	4.1	9.3	34.3	28.6	27.9
Assets	**8.2**	**7.7**	**12.7**	**38.9**	**89.5**	**86.7**
Equity	**6.0**	**5.2**	**10.5**	**35.7**	**60.4**	**62.3**
Share capital	0.3	0.3	0.4	0.5	0.5	0.5
Other	10.1	13.7	23.7	52.8	35.2	59.9
Net profit (loss)	-4.4	-8.9	-13.7	-17.6	24.7	1.9
Minority capital	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Long-term liabilities	**0.3**	**0.4**	**0.4**	**0.5**	**0.5**	**0.5**
Interest-bearing liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.3	0.4	0.4	0.5	0.5	0.5
Short-term liabilities	**1.9**	**2.2**	**1.9**	**2.7**	**28.5**	**23.8**
Interest-bearing liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Trade liabilities	0.9	1.0	1.2	2.7	3.9	5.9
Other	1.0	1.2	0.7	0.0	24.6	17.9
Liabilities	**8.2**	**7.7**	**12.7**	**38.9**	**89.5**	**86.7**
Net working capital	-0.4	-0.7	0.7	-0.7	23.2	20.9
Net debt	-6.1	-4.1	-9.3	-34.3	-28.6	-27.9
Net debt adj.	-6.1	-4.1	-9.3	-34.3	-28.6	-27.9
Net debt /EBITDA (x)	1.0	0.4	0.6	1.7	-1.1	-2.6
Net debt /equity (x)	-1.0	-0.8	-0.9	-1.0	-0.5	-0.4
ROE (%)	-	-	-	-	51%	3%
ROA (%)	-	-	-	-	39%	2%
Cash conversion cycle (days)	-	-	-	-	115	455
Inventory turnover (days)	-	-	-	-	128	513
Receivables turnover ratio (days)	-	-	-	-	21	44
Accounts payable turnover ratio (days)	-	-	-	-	34	102

Source: Bioceltix-historical data, Trigon - forecasts

Cash Flow (PLNm)

	2021	2022	2023	2024F	2025F	2026F
Cash flows from operating activities	**-4.0**	**-7.9**	**-14.7**	**-17.4**	**26.7**	**1.2**
Net profit (loss)	-4.4	-8.9	-13.7	-17.6	24.7	1.9
Amortization	0.4	0.4	0.4	0.5	1.3	3.8
Changes in working capital	-0.2	1.0	-1.1	-0.4	-23.9	2.3
Inventory changes	0.0	0.0	0.0	0.0	-25.0	0.4
Trade receivables change	-0.3	0.2	-1.5	-0.5	-0.1	-0.1
Trade liabilities change	0.0	0.8	0.5	0.1	1.3	2.0
Deffered income and other	0.2	-0.4	-0.4	0.0	24.6	-6.8
Cash flows from operating activities	**0.1**	**-0.4**	**-0.5**	**0.2**	**-32.0**	**-1.5**
CAPEX	0.0	-0.4	-0.5	0.0	-32.5	-2.0
Other	0.1	0.0	0.0	0.2	0.5	0.5
Cash flows from financial activities	**6.7**	**6.3**	**20.4**	**42.2**	**-0.4**	**-0.4**
Interest-bearing liabilities change	0.0	0.0	0.0	0.0	0.0	0.0
Revenues from shares emission	7.2	6.5	20.7	42.8	0.0	0.0
Dividend	0.0	0.0	0.0	0.0	0.0	0.0
Other	-0.4	-0.2	-0.3	-0.7	-0.4	-0.4
Net cash flows	2.9	-1.9	5.2	25.0	-5.7	-0.7
Cash opening balance	3.2	6.1	4.1	9.3	34.3	28.6
Closing balance of cash	6.1	4.1	9.3	34.3	28.6	27.9

Source: Bioceltix-historical data, Trigon - forecasts

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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 – Bioceltix 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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Short-term recommendations (particularly those designated as speculative) may be valid for shorter periods of time. Short-term recommendations designated as speculative involve a higher investment risk.
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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The valuation, methodology or underlying assumptions have not changed since the date when this Document was completed and first disseminated.
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