

MOLOGEN AG

Germany / Pharmaceutical/Biotechnology
 Primary Exchange: Frankfurt
 Bloomberg: MGN GR
 ISIN: DE0006637200

Update

RATING	BUY
PRICE TARGET	€ 28.90
Return Potential	504.6%
Risk Rating	High

LICENSE DEAL/RIGHTS ISSUE WOULD FULLY FUND PIVOTAL TRIAL

On 15 August Mologen signed a term sheet outlining the framework of an agreement assigning global development, manufacturing and commercialisation rights for lead compound lefitolimod to the Chinese/U.S. firm, Oncologie. The agreement is conditional on further funding of Oncologie in a mid-double digit million amount. Both the funding of Oncologie and the Oncologie-Mologen agreement are expected to close in Q1/19. The Oncologie-Mologen deal stipulates near-term (2018/19) funding of €23m (of which €14m to fund the pivotal IMPALA trial with metastatic colorectal cancer patients and €9m for additional combination trials of lefitolimod) as well as coverage of additional expenses (from 2019) of €20m. Development milestones would be up to ca. €200m, commercial milestones over €900m and tiered royalties would be set at a low double-digit percentage average rate. On 1 September Mologen announced a 1 for 2 rights issue intended to raise a net €17m. Up to 3.77m new shares are being offered at €4.70 per share between 7 September and 20 September. The issue proceeds together with the funding from Oncologie would fully fund the IMPALA trial, results of which are currently expected in April 2020. If lefitolimod is licensed to a third party outside Greater China (the most likely scenario in our view), Mologen will receive not less than 50% of the agreed payments for these territories. We had previously modelled double digit percentage royalties outside greater China. The assumption of single digit royalties outside Greater China has a negative impact on our price target. However, this is largely cancelled out by the positive impact of lower dilution and discount rates than we had previously modelled due to better funding visibility. We have also revised up our forecasts for milestone payments. Our new price target for the Mologen share is €28.9 (previously: €28.5): We maintain our Buy recommendation.

Oncologie backed by Chinese investors, managed by industry veterans
 Oncologie was founded at the end of 2017 and is headquartered in Boston, U.S. with operations in Boston and Shanghai. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018E	2019E	2020E
Revenue (€m)	0.04	0.07	0.05	6.00	7.00	42.50
Y-o-y growth	230.0%	89.7%	-36.5%	12666.0%	16.7%	n.a.
EBIT (€m)	-20.54	-20.98	-18.71	-12.87	-12.87	25.65
EBIT margin	n.a.	n.a.	n.a.	-214.4%	n.a.	100.0%
Net income (€m)	-20.54	-21.00	-19.28	-13.53	-13.53	24.99
EPS (basic) (€)	-4.95	-4.25	-2.80	-1.60	-1.14	2.09
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-15.18	-19.30	-19.11	-13.72	-14.44	19.13
Net gearing	-126.1%	-155.4%	n.m.	-206.4%	-41.0%	-93.7%
Liquid assets (€m)	24.59	20.52	6.52	20.52	6.07	25.21

RISKS

Risks to our price target include but are not limited to development, partnering, financial, and regulatory risks.

COMPANY PROFILE

MOLOGEN is a biopharmaceutical company based in Berlin specialising in the clinical development of innovative DNA-based and cell-based drugs in the fields of oncology and infectious diseases. The company's furthest developed product is lefitolimod for the treatment of metastatic colorectal carcinoma, small cell lung cancer and HIV. In addition a combination study of lefitolimod with Yervoy is being performed.

MARKET DATA

As of 10 Sep 2018

Closing Price	€ 4.78
Shares outstanding	7.54m
Market Capitalisation	€ 36.03m
52-week Range	€ 4.01 / 15.45
Avg. Volume (12 Months)	21,336

Multiples	2017	2018E	2019E
P/E	n.m.	n.m.	n.m.
EV/Sales	751.5	5.9	0.0
EV/EBIT	n.m.	n.m.	n.m.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2018

Liquid Assets	€ 6.21m
Current Assets	€ 8.01m
Intangible Assets	€ 0.01m
Total Assets	€ 8.04m
Current Liabilities	€ 5.80m
Shareholders' Equity	€ -3.28m

SHAREHOLDERS

Global Derivative Trading GmbH	<25.0%
Deutsche Balaton AG	5.0%
SIGNAL Krankenvers. a.G.	4.0%
Baloise Holding AG	4.0%
Axxion S.A.	3.0%
Free float	59.0%

It is backed by a group of Chinese investors including Pivotal bioVenture Partners China Fund, Nan Fung Life Sciences, China Merchant Bank Investments and Volcanics Ventures. The management team includes industry veterans with experience from Imclone, Eli Lilly, BMS, Sanofi and Daiichi.

August Mologen/Oncologie agreement is second step in collaboration The term sheet signed by Mologen and Oncologie in August represents the second step in the evolution of their collaboration. The first step was taken in February when Mologen granted Oncologie an exclusive license for the development, manufacture and commercialisation of lefitolimod in China, Hong Kong and Macao, Taiwan and Singapore. The February agreement encompassed a commitment to global co-development and stipulated payments to Mologen of €5m, of which €3m was transferred in April and €2m was carried over to the August agreement. The €2m was received by Mologen at the beginning of September through the issue of an interest-free convertible bond to Oncologie. The February agreement also entailed development and commercialisation milestones payable to Mologen relating to the Chinese market totalling €100m.

Closing of the deal – expected in Q1/19 – will be the third step The August agreement is much greater in scope than its February predecessor. Under the new agreement Oncologie will be solely responsible for the global development, manufacturing and commercialisation of lefitolimod and bear the corresponding expenses. Mologen and Oncologie have agreed on a three month exclusivity period extending to mid-November to negotiate final terms. The agreement is conditional on further funding of Oncologie in a mid-double digit million amount. Both the funding of Oncologie and the Oncologie-Mologen agreement are expected to close in Q1/19.

Figure 1: Key financial terms of August agreement between Mologen and Oncologie

Elements of consideration	In € m	Comments
Near-term consideration	23	To finance IMPALA study until read-out and extend development in further combinations and indications
1. Initial purchase price	3	
2. Payments for MGN's budgeted development expenses	7	Mainly for IMPALA
3. Funding of additional studies	9	Combination studies in immuno-oncology
4. Issuance of convertible bonds	4	Mandatory conversion, premium of 30%, interest free, 5 year term
• First convertible bond (€2m)		• issued on 3 September 2018; €9.702 new share
• Second convertible bond (€2m)		• At signing of contract
Coverage of additional expenses	~20	Future development activities, including regulatory interactions and production of drug material to support the future commercialisation of lefitolimod
Development milestones	up to 200	
Commercial milestones	ca. 900	Depending on sales
Tiered royalties at a low double-digit percentage average	n/a	Peak royalty rate at 16%

Source: Mologen

€14m of €23m near-term payment to finance IMPALA, initial lefitolimod production

€14m of the near term consideration of €23m will flow through Mologen's P&L/cashflow (1. and 2. in figure 1 above through the P&L, and 4. through the cashflow statement) and will be used mainly to finance the ongoing phase III IMPALA study of lefitolimod with metastatic colorectal cancer (mCRC) patients. Recruitment of IMPALA's 549 patients was completed in May 2017. Primary data analysis is currently expected in April 2020, although management indicated during the H1/18 results conference call on 9 August that this date may be revised before the end of this year. Part of the €14m will also be used to facilitate production through a contract manufacturing organisation of adequate quantities of lefitolimod to satisfy clinical and regulatory requirements. Oncologie will assume responsibility for production of lefitolimod once commercial quantities are required.

The €14m neatly refinances share/bond subscription facilities Mologen has a share subscription facility with the US Investor Global Corporate Finance (GCF). The shares can be issued to GCF at Mologen's discretion at 95% of 5-day VWAP.

The facility currently comprises 591,000 shares worth €2.8m after the 5% discount to VWAP. €11m of the original €12m convertible bond subscription agreement with European High Growth Opportunities Securitization Fund (EHGO) are also still available to Mologen. The conversion price is 90% of the Volume Weighted Average Price (VWAP) of Mologen's share price during the three trading days preceding the conversion but at least 80% of the VWAP of Mologen's share price during the 10 trading days preceding the issuance of the bonds. The €14m of the near-term consideration which will flow through Mologen's P&L/cashflow neatly refinances these share/bond subscription facilities at much more attractive terms.

€9m of the €23m to be used to finance further combination studies with lefitolimod

Mologen is already conducting a phase I trial of lefitolimod with the immune checkpoint inhibitor Yervoy in cooperation with the MD Anderson Cancer Center at the University of Texas. The dose escalation part of the study is expected to be completed in 2018. The trial with Yervoy is the first time that lefitolimod has been evaluated in combination with a checkpoint inhibitor. The new agreement with Oncologie indicates that the lefitolimod-Yervoy trial may be the first of several studies of lefitolimod in combination with other anti-cancer drugs.

Rights issue proceeds to be directed at IMPALA, lefitolimod manufacture, EnanDIM

We estimate combined cash consumption for 2018 and 2019 not including the additional combi studies, which will be sponsored by Oncologie, at €41m. €12m of this has already been financed, of which €5m came from Oncologie. Assuming the deal proceeds, €12m of our estimated required €29m will come from Oncologie. The rights issue is expected to finance the difference. The proceeds of the rights issue will cover that part of the IMPALA trial not financed by Oncologie as well as the manufacture of lefitolimod for clinical and regulatory requirements as mentioned above. In addition, Mologen will potentially spend some of the money on the development of its next generation immunomodulator EnanDIM with a view to starting clinical trials next year and aiming for clinical proof of concept in 2022. The term sheet gives Oncologie a Right of First Refusal to license EnanDIM.

Figure 2: FBe forecast financing breakdown 2018/2019

	2018E	2019E	2018E+2019E
Cash start of year	6,523	20,519	
Cash consumption	19,724	21,444	41,168
Financed by:			
Oncologie April 2018 and Q4 2018 payments	6,000		6,000
GCF share subscription	445		445
EHGO bond subscription	1,000		1,000
H1 2018 equity capital raising	5,275		5,275
Oncologie convertibles	4,000		4,000
September 2018 equity capital raise (net proceeds)	17,000		17,000
Financed by:			
Oncologie quarterly payments		7,000	7,000
Total financing	33,720	7,000	40,720
Cash end of year	20,519	6,075	
Proportion of financing from Oncologie	29.7%	100.0%	41.7%

Source: Mologen, FBe estimates

€20m from Oncologie for regulatory costs/commercial production from 2019 The August agreement also stipulates that Oncologie cover €20m of additional future development expenses relating to regulatory interactions and production of drug material to support future commercialisation of lefitolimod. The agreement points out that in the near term Mologen will be responsible for manufacturing activities to supply the clinical medication.

Potential further development of lefitolimod in ES-SCLC under evaluation The IMPULSE phase II trial of lefitolimod in 103 patients with extensive-stage small cell lung cancer (ES-SCLC) did not meet its primary endpoint of overall survival. This is not surprising as ES-SCLC is a very challenging indication. However, the study did demonstrate an overall survival benefit in comparison to the control arm in two important subgroups – patients with a low count of activated B cells (hazard ratio 0.53, 95% confidence interval 0.26-1.08) and patients with reported Chronic Obstructive Pulmonary Disease (hazard ratio 0.48, 95% confidence interval 0.20-1.17). The former group comprised 38 (43%) of a total of 88 patients for whom B cell data was available. The latter group numbered 25 of the 103 participants in the study. The B cell-related data is particularly interesting as it has positive implications for lefitolimod's efficacy against cancers other than SCLC. The size of the subgroups in the IMPULSE study are reflective of the overall patient population. Mologen is currently discussing potential further development of lefitolimod in ES-SCLC with clinical and scientific experts. However, the Mologen/Oncologie agreement does not mention ES-SCLC as an area of future development.

Development/regulatory and commercial milestones respectively €200m and €900m

Mologen stands to receive up to approximately €200m in development and regulatory milestone payments based on the success of IMPALA and additional indications the two parties intend to further develop. The agreement envisages commercial milestones of over €900m depending on future sales. Royalties are tiered at a low double-digit percentage average with a peak rate of 16%.

License payment split between Greater China/other territories so far undisclosed

Mologen will receive 100% of the milestone payments and royalties agreed for Greater China irrespective of whether Oncologie commercialises lefitolimod on its own or through licensees. In the event that Oncologie licenses lefitolimod out to a third party in territories outside greater China, MOLOGEN will receive 35% of all licensing receipts in the case of a positive read-out of the IMPALA study and otherwise 30%. Total licensing receipts payable for territories outside Greater China will be not less than 50% of the total agreed for these territories.

Figure 3 below shows changes to our forecasts. In the 2017 annual report Mologen guided towards an increase in cash consumption in 2018 vs. 2017. This guidance was changed in the H1/18 report to “comparable to or lower than the level of the previous year” due mainly to the later than expected start to preparations for contract manufacturing of lefitolimod. This explains €1.8m of the €4.8m increase in our 2018 EBIT forecast from €-17.7m to €-12.9m. The remaining €3m is the initial purchase price agreed with Oncologie. The increase in our 2019 sales forecast reflects the €7m of payments by Oncologie to finance budgeted development expenses at Mologen. We continue to assume a €42.5m milestone payment in 2020 following a positive IMPALA readout.

Figure 3: Changes to our forecasts

in €m	2018E			2019E			2020E		
	Old	New	Delta	Old	New	Delta	Old	New	Delta
Sales*	3.00	6.00	100.0%	0.00	7.00	-	42.50	42.50	0.0%
EBIT	-17.68	-12.87	-	-20.19	-12.87	-	22.17	25.65	15.7%
margin	neg.	neg.	-	neg.	neg.	-	neg.	neg.	-
Net income	-18.96	-13.53	-	-20.57	-13.53	-	21.79	24.99	14.7%
margin	neg.	neg.	-	neg.	neg.	-	neg.	neg.	-
EPS (in €)	-2.20	-1.60	-	-1.55	-1.14	-	1.45	2.09	44.2%

* including other operating income and upfront/milestone payment(s)

Source: First Berlin Equity Research estimates



We move our price target from €28.5 to €28.9 and maintain our Buy recommendation

If lefitolimod is licensed to a third party outside Greater China (the most likely scenario in our view), Mologen will receive "not less than 50%" of the agreed payments for these territories. We had previously modelled double digit percentage royalties outside greater China. The assumption of single digit royalties outside Greater China has a negative impact on our price target. However, this is to a large extent cancelled out by the positive impact of lower dilution and discount rates than we had previously modelled due to better funding visibility. We now use discount factors of 15% (previously 17.5%) and 20% (previously 22.5%) for markets outside Greater China and Greater China respectively. As figure 4 below shows, we have also revised up our forecasts for milestone payments. Our new price target for the Mologen share is €28.9 (previously: €28.5): We maintain our Buy recommendation.

Figure 4: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	€534.4M	€336.4M	-37.0%
Costs PV (4)	€204.3M	€209.5M	2.5%
NPV	€330.1M	€126.9M	-61.5%
Milestones PV	€51.8M	€183.6M	254.4%
Proforma net cash	€33.3M	€25.1M	-24.8%
Fair Value	€415.2M	€335.5M	-19.2%
Share Count	14,570K	11,595K	-20.4%
Price Target	€28.50	€28.94	1.6%

Source: First Berlin Equity Research estimates; Mologen AG

Figure 5: Pipeline valuation

Compound	Project ¹⁾	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin ²⁾	Discount Factor	Patent Life ³⁾	Time to Market
MGN1703	mCRC-EU	€91M	206K	€35,000	€7,216M	10%	€926M	7%	15.0%	8	4 Years
MGN1703	mCRC-US	€97M	131K	€58,333	€7,623M	10%	€978M	7%	15.0%	6	4 Years
MGN1703	SCLC-EU	€16M	24K	€25,000	€595M	50%	€392M	7%	15.0%	6	6 Years
MGN1703	SCLC-US	€14M	15K	€41,667	€628M	50%	€398M	7%	15.0%	4	6 Years
MGN1703	mCRC-PRC	€91M	247K	€24,500	€6,045M	10%	€1,164M	12%	20.0%	10	5 Years
MGN1703	SCLC-PRC	€28M	48K	€17,500	€837M	50%	€672M	12%	20.0%	10	5 Years
PACME PV		€336M			€32,809M		€6,698M				
Costs PV ⁴⁾		€209M									
NPV		€127M									
Milestones PV		€184M									
Proforma net cash		€25M									
Fair Value		€336M									
Proforma share count		11,595K									
Price Target		€28.94									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues.

This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research estimates



INCOME STATEMENT

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
Net product revenues	39	74	47	0	0	0
Milestone & upfront payments	0	0	0	6,000	7,000	42,500
Total revenue	39	74	47	6,000	7,000	42,500
Cost of materials	11,681	11,780	9,752	8,500	10,500	7,500
Gross profit	-11,642	-11,706	-9,705	-8,500	-10,500	-7,500
PACME (incl. milestone & upfront payments)	-11,642	-11,706	-9,705	-2,500	-3,500	35,000
Depreciation	121	408	49	40	44	48
Personnel costs	5,074	5,453	5,093	5,400	5,400	5,400
Other operating income (expense)	-3,702	-3,418	-3,860	-4,925	-3,925	-3,900
Operating income (EBIT)	-20,539	-20,985	-18,707	-12,865	-12,869	25,652
Net financial result	3	-18	-574	-660	-659	-659
Pre-tax income (EBT)	-20,536	-21,003	-19,281	-13,525	-13,528	24,992
Net income / loss	-20,536	-21,003	-19,281	-13,525	-13,528	24,992
Basic EPS (in EUR)	-4.95	-4.25	-2.80	-1.60	-1.14	2.09
EBITDA	-20,418	-20,577	-18,658	-12,825	-12,825	25,700
Ratios						
EBIT margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Expenses as % of PACME						
Personnel costs	n.m.	n.m.	n.m.	n.m.	n.m.	15.4%
Y-Y Growth						
Total revenues	225.0%	89.7%	-36.5%	12666.0%	16.7%	507.1%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



BALANCE SHEET

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
Assets						
Current assets, total	25,981	21,300	8,061	21,744	7,545	27,035
Cash and cash equivalents	24,592	20,520	6,523	20,519	6,075	25,207
Short-term Investments	0	0	0	0	0	0
Receivables	0	33	13	0	0	0
Inventories	28	13	16	25	30	128
Other current assets	1,361	734	1,509	1,200	1,440	1,700
Non-current assets, total	414	62	44	54	65	77
Property, plant & equipment	239	25	27	32	38	44
Goodwill & other intangibles	175	37	17	22	28	34
Other assets	0	0	0	0	0	0
Total assets	26,395	21,362	8,105	21,798	7,610	27,112
Shareholders' equity & debt						
Current liabilities, total	6,886	7,404	7,502	7,000	6,340	850
Short-term debt	8	3	9	0	0	0
Accounts payable	6,390	6,530	4,400	6,100	6,200	0
Other current liabilities	488	871	3,093	900	140	850
Long-term liabilities, total	6	2,121	5,474	9,420	9,420	9,419
Convertible bond	0	2,119	5,419	9,419	9,419	9,419
Long term debt	0	0	0	0	0	0
Deferred revenue	6	2	55	1	1	0
Shareholders' equity	19,503	11,837	-4,871	5,378	-8,150	16,843
Total consolidated equity and debt	26,395	21,362	8,105	21,798	7,610	27,112
Ratios						
Current ratio (x)	3.77	2.88	1.07	3.11	1.19	31.81
Quick ratio (x)	3.77	2.88	1.07	3.10	1.19	31.66
Net gearing	-126.1%	-155.4%	n.a.	-206.4%	-41.0%	-93.7%
Book value per share (€)	4.36	1.74	-0.71	0.46	-0.68	1.41
Net cash	24,584	18,398	1,095	11,100	-3,344	15,788
Return on equity (ROE)	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



CASH FLOW STATEMENT

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
EBIT	-20,539	-20,985	-18,707	-12,865	-12,869	25,652
Depreciation and amortization	121	408	49	40	44	48
EBITDA	-20,418	-20,577	-18,658	-12,825	-12,825	25,700
Changes in working capital	4,786	1,127	-705	-180	-905	-5,848
Other adjustments	546	198	251	-660	-659	-659
Operating cash flow	-15,086	-19,252	-19,112	-13,665	-14,389	19,193
CAPEX	-95	-44	6	-50	-55	-61
Free cash flow	-15,181	-19,296	-19,106	-13,715	-14,444	19,133
Debt financing, net	-2	-5	0	-9	0	0
Equity financing, net	26,207	12,706	477	23,720	0	0
Convertible bond	0	2,535	4,976	4,000	0	0
Changes in other financial assets	0	-18	0	0	0	0
Other Changes in Cash	5	6	-344	0	0	0
Net cash flows	11,029	-4,072	-13,997	13,996	-14,444	19,133
Cash, start of the year	13,563	24,592	20,520	6,523	20,519	6,075
Cash, end of the year	24,592	20,520	6,523	20,519	6,075	25,207
EBITDA/share	-4.90	-4.16	-2.73	-1.52	-1.08	2.15
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

FIRST BERLIN RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	9 January 2013	€60.70	Buy	€133.50
2...19	↓	↓	↓	↓
20	22 September 2017	€12.15	Buy	€66.50
21	20 November 2017	€13.10	Buy	€65.50
22	4 June 2017	€4.60	Buy	€28.50
23	Today	€4.78	Buy	€28.90

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First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy ¹	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

¹ The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

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Legally required information regarding

- key sources of information in the preparation of this research report
- valuation methods and principles
- sensitivity of valuation parameters

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