

PAION AG

Germany / Biotechnology
 Frankfurt Prime Standard
 Bloomberg: PA8 GR
 ISIN: DE000A0B65S3

Update

RATING PRICE TARGET

Return Potential
 Risk Rating

BUY
€ 4.30
 79.5%
 High

REMIMAZOLAM FILING IMMINENT IN JAPAN AND THE U.S.

PAION is due to file for market approval of remimazolam in Japan in the indication general anaesthesia in Q4/18 and in the U.S. in the indication procedural sedation in Q4/18 or Q1/19. In July, PAION started an EU Phase III clinical trial with remimazolam in general anaesthesia. The trial is on track and patient recruitment is expected to be completed in 2019. PAION's main priority over the next few years is to gain regulatory approval for remimazolam in as many countries for as many indications as possible. PAION estimates the peak sales opportunity for remimazolam at over USD500m annually for each of the three indications, procedural sedation, general anaesthesia and intensive care unit sedation. We maintain our Buy recommendation with an unchanged price target of €430.

Competitive advantage over incumbent products The two main incumbent products in the above-mentioned indications are midazolam which is used mainly in conscious sedation, and propofol which is used mainly in deep sedation. Remimazolam's advantage over midazolam is shorter onset/offset times and over propofol a clinically meaningful lower cardiodepressive effect.

String of regional partnerships Besides Cosmo for the U.S. and Mundipharma for Japan, PAION has concluded regional partnerships for remimazolam in countries including China, South Korea, Canada, Russia and Turkey. The Russian and South Korean partners plan to file for market approval of remimazolam in general anaesthesia in Q1/19 and 2020 respectively. All other partners plan to file in their regions based on the U.S. or Japanese dossier.

Long term plan to make PAION an acute/critical care specialist Management has outlined plans beyond the international roll-out of remimazolam. Through a mixture of forward integration and partnering, PAION plans to move out of the small-cap and into the mid-cap space and become an acute/critical care specialist. Meanwhile, the product portfolio is to be enriched with products used by anesthesiologists and emergency physicians.

FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018E	2019E	2020E
Revenue (€m)	0.07	4.26	5.81	3.00	17.64	29.99
Y-o-y growth	n.a.	n.a.	36.4%	-48.4%	487.9%	70.1%
EBIT (€m)	-34.09	-25.08	-15.87	-13.75	-6.26	5.79
EBIT margin	1.0%	2.0%	3.0%	4.0%	5.0%	6.0%
Net income (€m)	-28.21	-20.12	-12.09	-11.23	-3.04	9.01
EPS (diluted) (€)	-0.56	-0.38	-0.20	-0.18	-0.05	0.14
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-26.32	-11.78	-17.75	-12.04	-2.60	3.04
Net gearing	-91.9%	-120.7%	-98.5%	-91.8%	-94.7%	-76.7%
Liquid assets (€m)	32.68	30.11	24.84	17.84	20.25	23.28

RISKS

Risks to our price target include but are not limited to: drug development, finding development partners on favourable terms, financial, and legal risks.

COMPANY PROFILE

PAION is a specialty pharmaceutical company headquartered in Aachen (Germany) with operations in Cambridge (United Kingdom). PAION's lead substance, remimazolam, is an intravenous ultra-short-acting benzodiazepine anaesthetic that has completed phase III clinical development for procedural sedation.

MARKET DATA

As of 19 Nov 2018

Closing Price	€ 2.40
Shares outstanding	63.86m
Market Capitalisation	€ 152.94m
52-week Range	€ 2.01 / 2.71
Avg. Volume (12 Months)	80,559

Multiples	2017	2018E	2019E
P/E	n.a.	n.a.	n.a.
EV/Sales	22.9	44.4	7.5
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2018

Liquid Assets	€ 19.82m
Current Assets	€ 23.45m
Intangible Assets	€ 2.28m
Total Assets	€ 25.81m
Current Liabilities	€ 3.91m
Shareholders' Equity	€ 21.91m

SHAREHOLDERS

Cosmo Pharmaceuticals	9.1%
TIAA-CREF	3.0%
Free Float	87.9%



Some R&D spend shifted into 2019, but EU phase III general anesthesia trial on track

9M/18 results were close to our expectations except for the R&D line for which management has now changed FY guidance. Revenue came in at €0.8m (9M/17: €5.1m) and the net result was €-8.8m (9M/17: €-8.5m). Revenue during 9M/18 stemmed from partial revenue recognition of the upfront payment of €1m received from Mundipharma with respect to the remimazolam license agreement for Japan concluded in 2017. 9M/17 revenues resulted primarily from the license agreement with U.S. license partner Cosmo. The 9M/18 net result was close to the prior year level despite a €4m decline in revenues mainly because of lower R&D spending. R&D expense came in at €9.1m (9M/17: €13.5m). The €4.4m reduction is a function of the completion of phase III and I trials of remimazolam mainly in connection with the U.S. development programme.

Figure 1: 9M/18 results vs. our forecasts

in EURm	9M/18A	9M/17E	Delta	9M/17A	Delta
Total revenue*	0.76	1.00	-24.2%	5.10	-85.1%
R&D expenses	9.12	11.04	-17.4%	13.53	-32.6%
S,G&A expenses	2.57	2.61	-1.6%	2.80	-
EBT	-10.83	-16.87	-	-11.29	-
Tax credit	2.07	2.24	-7.8%	2.79	-25.8%
Net income	-8.76	-10.42	-	-8.51	-
margin	neg.	neg.	-	neg.	-
EPS (dil., in EUR)	-0.14	-0.17	-	-0.15	-

* including other operating income such as milestone payments

Source: PAION, First Berlin Equity Research estimates

Filing milestones in Japan and U.S. €2m and €7.5m respectively PAION has altered its guidance for the full year net result from a loss of €12.5-15m to a loss of €10-12.5m. The change stems from a reduction in expected R&D expenditure from €15-17m to €12-14m. During the analysts' conference call following the 9M results, management emphasised that the reduction does not relate to a delay in the EU phase III trial of remimazolam in general anesthesia. Completion of recruitment is still expected in 2019. However, some R&D expenses have been shifted into 2019. PAION's FY 2018 revenue guidance is unchanged at ca. €3m. Management expects to book a €2m milestone in connection with filing for approval of remimazolam in Japan in the indication general anesthesia in Q4/18. Filing for approval of remimazolam in the U.S. in the indication procedural sedation is expected either in Q4/18 or Q1/19. In the event that filing occurs in Q4/18, PAION will book a €7.5m milestone payment in its P&L account. This figure is not currently included in 2018 guidance.

Figure 2: Change in FY guidance in 9M/18 report

in EURm	FY/18 Guidance New	FY/18 Guidance Old	Delta
Total revenue*	ca. €3m	ca. €3m	0.0%
R&D expenses	ca. €12-€14m	ca. €15-€17m	ca. -18.8%
S,G&A expenses	ca. €3.5-€4m	ca. €3.5-€4m	0.0%
Tax credits	ca. €2.5m	ca. €3m	ca. -16.7%
Net result	ca. €-10.0- €-12.5m	ca. €-12.5- €-15m	ca. 18.2%

* including other operating income such as milestone payments

Source: PAION

Priority is approval for remimazolam in as many countries/applications as possible

Management has confirmed that the company's main priority over the next few years is to gain regulatory approval for remimazolam in as many countries for as many indications as possible.



In recent years PAION has entered into development and commercialization collaborations with partners on international markets on which it does not intend to directly conduct sales and marketing activities. These collaborations are listed in figure 3 below.

Figure 3: Development and commercialisation collaborations on international markets

	Upfront milestone payments		Royalty rate
	Total received	Maximum outstanding amount	
Ono, Japan (2007) (terminated in 2015)	USD8.0m	None	None
Yichang Humanwell, China (2012)	€3.0m	€4.0m	10%
Hana Pharm, S.Korea (2013)	€1.0m	€2.0m	10%
R Pharm, CIS (2013)	€1.0m	€3.0m	Low double-digit
(T)R Pharm, Turkey (2013)	€1.0m	€3.0m	Low double-digit
(T)R Pharm, MENA (2013)	€1.5m	€5.5m	Low double-digit
Pharmascience, Canada (2014)	€0.4m*	€3.7m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	€20.0m**	€42.5m	20-25%***
Mundipharma, Japan (2017)	€1.0m	€25.0m	Up to over 20%***
Total	€34.8m	ca. €88.7m	

* This amount relates to the premium received in the course of the private placement in the amount of €4m in July 2014 which was disclosed as revenues in 2014.

** Comprising € 10m received via private placement in June 2016 and via capital increase with subscription rights conducted in February 2017 as well as the received upfront payment of € 10m.

*** Subject to adjustment under specific circumstances, but not below 15% of net sales

**** Tiered royalties starting in the low double-digits to over 20%

Source: PAION

Russian/S. Korean partners plan filing for approval in Q1/19 and 2020 respectively

Outside the U.S. and Japan (discussed above), there have been significant developments so far in 2018 in China, Russia and South Korea. Earlier this month R-Pharm announced the successful completion of a Phase III trial in general anesthesia and now plans to file for market approval in Q1/19. In South Korea Hana Pharm completed recruitment of a Phase III trial in general anesthesia in October. Hana Pharm plans to file for market approval in 2020 following the establishment of local production. Pharmascience (Canada) and TR-Pharm (Turkey, the Middle East and North Africa) plan to file for market approval in their respective territories based on the U.S. or Japanese dossier.

NDA for remimazolam in procedural sedation accepted by China's NMPA On 16 November PAION stated that China's National Medical Products Administration (NMPA) had accepted for review Yichang Humanwell's New Drug Application (NDA) for remimazolam in procedural sedation. The NDA submission triggers a milestone payment of EUR 0.5 million from Yichang Humanwell.

PAION estimates the peak sales opportunity for remimazolam at over USD500m annually for each of the three indications, procedural sedation, general anesthesia and intensive care unit (ICU) sedation. The two main incumbent products in these indications are midazolam which is used mainly in conscious sedation and propofol which is used mainly in deep sedation. We believe that remimazolam's advantages over midazolam and propofol will enable it to gain market share from both products.

Advantages over incumbent products midazolam and propofol On the key US procedural sedation market, propofol is most widely used in the eastern states, and midazolam in the western part of the country. Data from Paion's U.S. phase III study with remimazolam in procedural sedation suggested that the time saved through using remimazolam instead of midazolam is likely to exceed twenty minutes. This is a substantial time saving on a typical colonoscopy procedure time of 30-60 minutes.



The US colonoscopy market is currently seeing trends towards lower reimbursement per procedure and “bundling” or a contracted flat fee for the total cost of each colonoscopy. In this environment, physicians are looking for ways to maintain their income. Remimazolam’s advantage over midazolam of shorter onset/offset times and over its other main prospective competing product, propofol, of not requiring an anesthetist is a clear potential answer to this problem.

The current standard of care for induction of general anesthesia is propofol. A major problem with propofol is that it causes hypotension. During surgery vasopressors are routinely used to maintain blood pressure in the normal range and counteract pronounced blood pressure decreases. Vasopressors are however known to impair the microcirculation in vital organs and thus have a negative effect on short, mid and long-term outcomes. In the course of Ono’s phase II/III trial with remimazolam for general anesthesia, remimazolam and propofol were intravenously administered to 375 patients. Two remimazolam groups received induction doses of 6 mg/kg/h or 12 mg/kg/h, 150 subjects per group and 75 patients received a standard dose of propofol. The incidence rates of decrease in blood pressure were 35.3%, 34.7% and 60.0% in 6 mg/kg/h and 12 mg/kg/h of remimazolam and propofol groups, respectively. This suggests that remimazolam has a clinically meaningfully lower cardiodepressive effect compared with propofol. The forthcoming EU phase III trial of remimazolam in the indication general anesthesia has been designed to confirm this.

Long term plan to make PAION an acute/critical care specialist PAION has outlined plans beyond the international roll-out of remimazolam. The intention is to move the company out of the small-cap and into the mid-cap space by turning PAION into an acute/critical care specialist. Management intends to achieve this through forward integration in selected regions and partnering in others. Meanwhile, management intends to enrich the product portfolio to encompass a range of products used by anesthesiologists and emergency physicians. At present, these plans are still at an early stage and we have not taken account of them in our forecasts.

Changes to our forecasts (see figure 4 below) relate to the revision to guidance regarding R&D announced by management in the 9M/18 report. For the first time, we also show full 2020 numbers.

Figure 4: Changes to our forecasts

in EURm	2018E			2019E			2020E
	Old	New	Δ	Old	New	Δ	
Revenues	0.00	0.00	n.a.	1.84	1.84	0.0%	21.99
Other operating income	3.00	3.00	0.0%	15.80	15.80	0.0%	8.00
Total revenues	3.00	3.00	0.0%	17.64	17.64	0.0%	29.99
EBIT	-16.75	-13.75	n.a.	-6.26	-6.26	n.a.	5.79
margin	neg.	neg.	-	neg.	neg.	-	neg.
Net income	-13.73	-11.23	n.a.	-3.05	-3.04	n.a.	9.01
margin	neg.	neg.	-	neg.	neg.	-	30.1%
EPS (dil., in EUR)	-0.22	-0.18	n.a.	-0.05	-0.05	n.a.	0.14

Source: First Berlin Equity Research estimates

Buy recommendation and price target of €4.30 maintained We expect the end 9M/18 cash position of €19.8m together with tax credits from the British tax authorities and milestones from regulatory approval in the U.S. and Japan to cover planned activity until early 2020. This includes filing in the U.S. and Japan as well as the EU phase III study of remimazolam in the indication general anesthesia. However, filing for approval in the EU in this indication is expected to require an additional €10m which will be only partially covered by potential further milestone payments. We continue to model a €5m capital increase in 2019. Our price target is unchanged at €4.30 and we maintain our Buy recommendation.



Figure 5: Pipeline valuation model

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
Remimazolam	PS EU	€90.6M	25,300K	€14	€348.5M	25%	€117.3M	30%	15%	15	3 Years
Remimazolam	PS US	€150.3M	20,000K	€20	€400.0M	50%	€258.7M	20%	15%	13	2 Years
Remimazolam	PS CAN	€7.1M	1,056K	€20	€21.1M	50%	€13.7M	18%	15%	13	2 Years
Remimazolam	GA EU	€198.3M	29,000K	€40	€1,160.0M	20%	€312.2M	30%	15%	15	3 Years
Remimazolam	GA US	€84.1M	23,925K	€40	€957.0M	20%	€247.6M	20%	15%	13	4 Years
Remimazolam	GA JAP	€92.2M	10,000K	€40	€400.0M	25%	€134.6M	8%	15%	15	1 Year
Remimazolam	GA CHN	€18.1M	51,000K	€28	€1,405.0M	10%	€189.1M	10%	15%	15	4 Years
Remimazolam	PS CHN	€9.9M	33,260K	€10	€346.5M	10%	€46.6M	10%	15%	15	3 Years
Remimazolam	GA KOR	€7.4M	3,750K	€28	€103.3M	25%	€34.8M	10%	5%	15	3 Years
Remimazolam	GA CIS/MENA/TUR	€67.5M	55,247K	€28	€1,566.6M	10%	€210.8M	12%	15%	15	2 Years
Remimazolam	ICU US	€15.7M	1,561K	€250	€390.2M	25%	€126.2M	20%	15%	13	6 Years
Remimazolam	ICU EU	€33.3M	2,439K	€167	€406.5M	25%	€136.8M	30%	15%	15	5 Years
Remimazolam	ICU Japan	€4.2M	606K	€167	€101.0M	25%	€34.0M	18%	15%	15	6 Years
PACME PV		€778.6M									
Costs PV (4)		€566.2M									
NPV		€212.4M									
Milestones PV		€45.9M									
Pro forma net cash		€24.4M									
Fair Value		€282.7M									
Pro forma share count		65,877K									
Price Target		€4.30									

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

PS EU = Procedural Sedation in the EU

PS US = Procedural Sedation in the US

PS CAN = Procedural Sedation in Canada

GA EU = General Anaesthesia in the EU

GA US = General Anaesthesia in the US

GA JAP = General Anaesthesia in Japan

GA CHN = General Anaesthesia in China

GA KOR = General Anaesthesia in South Korea

GA CIS/MENA/TUR = General Anaesthesia in the Commonwealth of Independent States, Middle East & North Africa, and Turkey

ICU US = General Anaesthesia in Intensive Care Units in the US

ICU EU = General Anaesthesia in Intensive Care Units in the EU

Other projects: GGF2 (HF) and Solulin (HPH)

HF = Heart Failure

HPH = Haemophilia

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, CapEx and working capital; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

Figure 6: Changes to pipeline valuation model

	Old	New	Delta
NPV	€200.4M	€212.4M	6.0%
Milestones PV	€44.0M	€45.9M	4.3%
Pro Forma Net Cash	€31.0M	€24.4M	-21.2%
Fair Value	€275.4M	€282.7M	2.7%
Diluted Share Count	€64.3M	€65.9M	2.4%
Fair Value Per Share	€4.30	€4.30	0.0%

Source: First Berlin Equity Research



INCOME STATEMENT

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
Net revenues	0	0	0	0	1,836	21,994
Other op. inc. (including milestones)	72	4,262	5,811	3,000	15,800	8,000
Total revenue	72	4,262	5,811	3,000	17,636	29,994
Cost of goods sold	11	0	0	0	0	0
Gross profit	61	4,262	5,811	3,000	17,636	29,994
G&A	5,729	5,129	3,828	3,750	3,900	4,200
R&D	29,385	23,408	17,854	13,000	20,000	20,000
Other operating income (expense)	965	-807	-2	0	0	0
Operating income (EBIT)	-34,088	-25,082	-15,872	-13,750	-6,264	5,794
Net financial result	42	21	20	19	20	20
Pre-tax income (EBT)	-34,046	-25,061	-15,852	-13,731	-6,244	5,814
Income taxes	5,834	4,944	3,759	2,500	3,200	3,200
Net income / loss	-28,212	-20,118	-12,093	-11,231	-3,044	9,014
Diluted EPS	-0.56	-0.38	-0.20	-0.18	-0.05	0.14
EBITDA	-33,742	-24,758	-15,626	-13,560	-6,124	5,934
Ratios						
EBIT margin	n.m.	n.m.	n.m.	n.m.	n.m.	19.3%
EBITDA margin	n.m.	n.m.	n.m.	n.m.	n.m.	19.8%
Net margin	n.m.	n.m.	n.m.	n.m.	n.m.	30.1%
Cash Coverage of Expenses						
Cash / G&A	5.7x	5.9x	6.5x	4.8x	5.2x	5.5x
Cash / R&D	1.1x	1.3x	1.4x	1.4x	1.0x	1.2x
Y-Y Growth						
Total revenue	-97.9%	5851.0%	36.4%	-48.4%	487.9%	70.1%
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	40,051	35,128	29,357	23,841	27,021	37,180
Cash and cash equivalents	32,680	30,111	24,839	17,841	20,245	23,285
Short-Term Investments	0	0	0	0	0	0
Receivables	0	0	37	0	275	3,299
Inventories	0	0	0	0	0	3,596
Other current assets	7,371	5,017	4,481	6,000	6,500	7,000
Non-current assets, total	3,417	2,855	2,529	2,359	2,239	2,119
Property, plant & equipment	56	167	114	84	54	24
Goodwill & other intangibles	3,362	2,688	2,415	2,275	2,185	2,095
Other Assets	0	0	0	0	0	0
Total assets	43,468	37,984	31,885	26,200	29,259	39,298
Shareholders' equity & debt						
Current Liabilities, Total	7,901	13,040	6,656	6,771	7,884	8,944
Convertible bond	0	0	0	0	0	0
Short-term debt	0	0	0	0	0	0
Accounts payable	7,332	6,353	5,921	5,921	7,000	8,000
Milestone	0	5,730	0	0	0	0
Provisions	224	555	391	0	9	44
Other current liabilities	344	403	344	850	875	900
Longterm liabilities, total	6	0	0	0	0	0
Convertible bond	0	0	0	0	0	0
Long-term debt	0	0	0	0	0	0
Provisions	0	0	0	0	0	0
Deferred revenue	6	0	0	0	0	0
Shareholders' equity	35,562	24,943	25,229	19,429	21,375	30,354
Total consolidated equity and debt	43,468	37,984	31,885	26,200	29,259	39,298
Ratios						
Current ratio (x)	5.07	2.69	4.41	3.52	3.43	4.16
Quick ratio (x)	5.07	2.69	4.41	3.52	3.43	3.75
Net gearing	-91.9%	-120.7%	-98.5%	-91.8%	-94.7%	-76.7%
Book value per share (€)	0.70	0.45	0.41	0.30	0.33	0.48
Return on equity (ROE)	-57.5%	-66.5%	-48.2%	-50.3%	-14.9%	34.9%



CASH FLOW STATEMENT

All figures in EUR '000	2015	2016	2017	2018E	2019E	2020E
Net result	-28,212	-20,118	-12,093	-11,231	-3,044	9,014
Depreciation and amortization	125	759	347	190	140	140
Changes in working capital	3,999	1,137	-911	-976	329	-6,095
Milestone	0	5,730	-5,730	0	0	0
Net taxes received	-3,269	585	838	0	0	0
Other items	1,071	321	-170	0	0	0
Operating cash flow	-26,287	-11,586	-17,720	-12,018	-2,576	3,060
CAPEX	-33	-192	-25	-20	-20	-20
Free cash flow	-26,320	-11,778	-17,745	-12,038	-2,596	3,040
Debt financing, net	0	0	0	0	0	0
Convertible bond financing, net	0	0	0	0	0	0
Equity financing, net	22	9,212	12,494	5,040	5,000	0
Other changes in cash	66	-2	-22	0	0	0
Net cash flows	-26,232	-2,568	-5,273	-6,998	2,404	3,040
Cash, start of the year	58,912	32,680	30,111	24,839	17,841	20,245
Cash, end of the year	32,680	30,111	24,839	17,841	20,245	23,285
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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	2 April 2012	€0.79	Buy	€2.00
2...34	↓	↓	↓	↓
35	27 March 2017	€2.19	Buy	€4.40
36	4 July 2017	€3.04	Buy	€4.40
37	10 April 2018	€2.23	Buy	€4.30
38	Today	€2.40	Buy	€4.30

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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.

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