Jaguar Health, Inc.

USA / Biotechnology
Nasdaq
Bloomberg: JAGX US
ISIN: US47010C8055

Pipeline update

RATING	**BUY**
PRICE TARGET	**$ 40.00**
Return Potential	1500.0%
Risk Rating	High

FDA SUPPORTS JAGUAR'S STRATEGY IN BREAST CANCER THERAPY-RELATED DIARRHOEA

Jaguar has held a Type C face-to-face meeting with the FDA to discuss statistically significant responder data from the prespecified subgroup of breast cancer patients in the phase 3 OnTarget trial for crofelemer in cancer therapy-related diarrhoea (CTD). Although the overall prophylactic trial for all solid tumour types did not meet its primary endpoint, the breast cancer subgroup, as presented at the San Antonio Breast Cancer Symposium (SABCS) in the US in December 2024, showed statistical significance in the responder analysis over the 3-month treatment period. These results prompted Jaguar to propose two parallel regulatory paths to the FDA: (1) a new pivotal treatment trial in metastatic breast cancer (mBC) patients and (2) an expanded access programme (i.e. compassionate use) for those patients with BC that are ineligible for the next planned treatment trial. The FDA accepted both proposed strategies. Jaguar intends to submit a pivotal trial protocol and will also pursue an orphan drug designation, as the mBC disease qualifies under orphan criteria. The company also plans to seek either Breakthrough Therapy and/or Fast Track designation to support an expedited approval process. Jaguar is leveraging a constructive FDA dialogue, orphan designation potential, and expedited pathways to advance crofelemer towards approval in the US. However, success will depend on executing the pivotal trial and securing funding in the interim. We have updated our SOTP model to reflect the higher forecast dilution due to the current lower share price, resulting in a price target of USD 40 (previously: USD 60). We confirm our Buy rating (upside >1,000%).

FDA meeting clarifies potential twin-track path to approval for crofelemer in mBC patients with CTD Jaguar Health has announced a productive Type C meeting with the FDA to discuss the statistically significant results of a responder analysis from the phase 3 OnTarget trial in BC patients. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2022	2023	2024	2025E	2026E	2027E
Revenue ($ m)	12.0	9.8	11.7	12.6	34.9	28.2
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT ($ m)	-34.4	-34.3	-30.8	-25.5	0.9	0.7
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income ($ m)	-48.4	-41.9	-39.3	-30.3	-3.8	-2.9
EPS (diluted) ($)	-36.18	-1.79	-130.69	-10.11	-0.57	-0.40
DPS ($)	0.00	0.00	0.00	0.00	0.00	0.00
FCF ($m)	-34.8	-33.2	-29.6	-22.3	1.3	-0.1
Net gearing	832.4%	-130.4%	-81.9%	-97.8%	-66.7%	-49.4%
Liquid assets ($ m)	5.5	6.5	8.0	5.0	5.6	4.8

RISKS

Risks include, but are not limited to development, regulatory, competition and financial risks.

COMPANY PROFILE

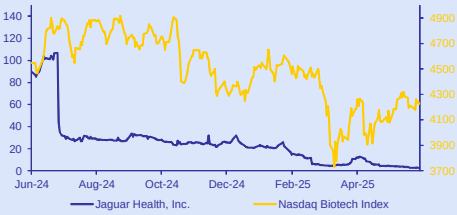
Jaguar Health Inc is a US-based, commercial-stage pharmaceutical company leveraging plant-based, sustainably derived medicines for the treatment of gastrointestinal disorders. The company's lead product, crofelemer (marketed as Mytesi®), is FDA-approved for the niche indication of symptomatic relief of non-infectious diarrhoea in adult HIV/AIDS patients on antiretroviral therapy.

MARKET DATA

As of 27 Jun 2025	
Closing Price	$ 2.50
Shares outstanding	0.67m
Market Capitalisation	$ 1.69m
52-week Range	$ 2.50 / 106.75
Avg. Volume (12 Months)	53,401

Multiples	2024	2025E	2026E
P/E	n.a.	n.a.	n.a.
EV/Sales	3.0	2.8	1.0
EV/EBIT	n.a.	n.a.	38.6
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Mar 2025	
Liquid Assets	$ 5.69m
Current Assets	$ 30.44m
Intangible Assets	$ 18.01m
Total Assets	$ 51.46m
Current Liabilities	$ 28.21m
Shareholders' Equity	$ 0.83m

SHAREHOLDERS

Uptown Capital and Streeterville	9.9%
Freefloat & others	90.1%

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While the overall study did not meet its primary endpoint, data from a large subgroup of mBC patients based on responder analysis demonstrated statistically significant benefit in managing cancer therapy-related diarrhoea (CTD) using crofelemer (for more details, see our initiating coverage report from 19 May 2025). According to management, the Type C face-to-face meeting with the FDA went very well. The company and the FDA discussed two concurrent regulatory pathways:

1. **Pivotal Trial Pathway:** Jaguar plans to submit a protocol for a small, focused pivotal treatment trial in mBC patients with cancer therapy-related diarrhoea (CTD) with selected targeted therapies to support a supplemental NDA. While the agency accepted results from the responder analysis as a secondary endpoint and has no objection to its use in future studies, it would like to see more justification of its clinical relevance. To this end, Jaguar intends to conduct a new survey which will generate fresh data on the mBC population, enhancing the relevance and design of the upcoming trial. The planned treatment trial will focus on mBC patients on selected targeted therapies such as abemaciclib, pertuzumab, and capivasertib. We expect Jaguar to start the survey shortly, which could lead to finalisation and submission of the study protocol to the FDA before the end of the year.
2. **Expanded Access Programme (EAP):** In parallel, Jaguar will seek authorisation to open an EAP for breast cancer patients who are ineligible for the planned pivotal treatment trial, including those with non-metastatic breast cancer (e.g., adjuvant or neoadjuvant settings) or those otherwise excluded from the trial population (e.g., comorbidities). EAP — sometimes called compassionate use — is a regulatory pathway that allows patients with serious or life-threatening conditions to gain access to investigational (i.e., not yet FDA-approved for a specific use) drugs outside of a clinical trial when no comparable or satisfactory alternatives are available. This would give Jaguar the opportunity to collect additional real-world data to support the ongoing pivotal trial, raise awareness and familiarise physicians with the drug. An EAP would also be potentially beneficial once the drug is approved as these patients could also provide immediate revenue. Unfortunately, EAP patients are not usually eligible for reimbursement, and sponsors customarily provide the drug free of charge or at cost, which would place an additional financial burden on Jaguar.

mBC may qualify for orphan drug and fast track designations… The estimated mBC population of ~150k patients in the US qualifies as an orphan population, allowing Jaguar to pursue Orphan Drug Designation (ODD) for crofelemer in this indication. We expect Jaguar to prepare the ODD application and submit it during the coming months. Given the drug's novel mechanism and the urgent need in this population, the company also intends to apply for Breakthrough Therapy and/or Fast Track designation, potentially enabling an expedited review process. Jaguar emphasized that crofelemer's safety is well established in its existing HIV-related diarrhoea indication, with no serious adverse events attributed to the drug.

…as well as potential additional support as a rare disease from President Trump's policies Jaguar's multi-pronged crofelemer strategy is in line with the company's established strategy and also aligns with recent signals from President Donald Trump's nominated FDA Commissioner, Marty Makary, about accommodating rare and serious conditions through pathways based on plausible mechanisms, especially in underserved populations.

UPDATE ON THE INTESTINAL FAILURE RARE DISEASE PROGRAMMES

Enrolment of placebo-controlled phase 2 trials in intestinal failure for paediatric MVID and adult SBS-IF patients are making good progress Jaguar has provided an update on its crofelemer development programme targeting intestinal failure caused by microvillus inclusion disease (MVID) and short bowel syndrome (SBS-IF). The company reported that enrolment in its placebo-controlled phase 2 trial for paediatric MVID patients has reached ~25% of the planned minimum of 6-8 patients, while its placebo-controlled phase 2 trial for adult SBS-IF patients has surpassed 10% of the planned 18 patients, with patient screening ongoing for both studies. The company anticipates completing its MVID phase 2 trial by mid-2026 and the SBS-IF in H2 2026.

The latest results of an investigator-initiated trial (IIT) presented at the 2025 Annual ELITE PED-GI Congress in Abu Dhabi were very encouraging The initial results of an investigator-initiated trial (IIT) presented in Abu Dhabi on 26 April show that Crofelemer was able to reduce the need for total parenteral nutrition (TPN) by up to 27% in an MVID patient and 12.5% in an SBS-IF patient, while reducing stool output and improving oral intake, which is significant for these patients. A third paediatric SBS-IF patient is currently undergoing treatment. Further details on Jaguar's MVID and SBS-IF programmes can be found in our Initiating Coverage Report from 19 May 2025.

Attractive assets which are eligible for expedited approval Given MVID’s ultra-rare status and the promising early data, Jaguar is exploring expedited regulatory pathways, including potential inclusion in the European Medicines Agency’s PRIME programme and the FDA’s Breakthrough Therapy designation. Additional IIT results expected in 2025 may further support early access and regulatory approval for crofelemer in Europe and the US.

Partnerships are a key focus for the rare disease intestinal failure programmes Jaguar is actively seeking business development partnerships to license the development and commercialisation rights for its intestinal failure products, with the goal of securing non-dilutive funding. CEO Lisa Conte pointed out that the company is holding productive discussions with potential partners in line with this strategic direction.

VALUATION MODEL

Unchanged rating at lower price target Jaguar Health's recent FDA engagement marks a significant step toward a potential regulatory pathway for crofelemer in the treatment of CTD in mBC patients. This targeted indication not only addresses a critical unmet need in oncology supportive care, but also complements Jaguar's strategic focus on rare diseases. The CTD indication synergizes with the company's ongoing orphan drug development efforts for its new crofelemer oral powder formulation targeting the rare diseases microvillus inclusion disease (MVID) and short bowel syndrome with intestinal failure (SBS-IF), reinforcing its commitment to providing therapeutic solutions for underserved patient populations. We have updated our SOTP model to reflect the higher estimated dilution given the current lower share price, resulting in a price target of USD 40 (previously: USD 60). We confirm our Buy rating (upside >1,000%). Over the next twelve months, we expect positive news flow on progress in the development and approval process of crofelemer in all three ongoing rare disease indications, and particularly partnering, to halt the recent downward trend and trigger appreciation of Jaguar's share price.

Table 1: "Sum-of-the-parts" valuation model

Compound	Project[1)]	Present Value	Patient Pop (K)	Treatment Cost (USD)	Market Size (USDM)	Market Share (%)	Peak Sales (USDM)	PACME Margin[2)] (%)	Discount Factor (%)	Time to Market (years)
Crofelemer	HIV - US	USD 42.7M	797K	1,685	1,342.9M	1%	15.5M	45%	16.0%	Market
Gelclair	Oral Mucositis - US	USD 16.9M	100K	540	54.0M	10%	9.1M	45%	16.0%	Market
Crofelemer	mBCTD - US	USD 70.8M	150K	1,685	1,011.0M	10%	118.5M	32%	16.0%	4
Crofelemer	mBCTD - EU	USD 36.5M	179K	1,180	845.2M	10%	96.0M	20%	16.0%	4
Crofelemer	MVID - US	USD 32.3M	0.1K	400,000	40.0M	50%	28.5M	45%	16.0%	2
Crofelemer	MVID - EU	USD 5.7M	0.1K	200,000	20.0M	50%	12.7M	20%	16.0%	2
Crofelemer	SBS-IF - US	USD 68.4M	1.5K	300,000	450.0M	20%	103.4M	32%	16.0%	4
Crofelemer	SBS-IF - EU	USD 20.8M	1.5K	150,000	225.0M	20%	54.9M	20%	16.0%	4
PACME PV		USD 294.0M			3,988.1M		438.5M			
Costs PV[3)]		USD 105.9M								
NPV		USD 188.1M								
Milestones PV		USD 21.3M								
Net cash (proforma)		USD 30.3M								
Fair Value		USD 239.6M								
Share Count (proforma)		5,991K								
Price Target		USD 40.00								

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

INCOME STATEMENT

All figures in USD '000	2022	2023	2024	2025E	2026E	2027E
Revenue	**11,956**	**9,761**	**11,560**	**12,556**	**14,865**	**18,183**
Upfront payments	**0**	**0**	**129**	**0**	**20,000**	**10,000**
Total revenue & other income	**11,956**	**9,761**	**11,689**	**12,556**	**34,865**	**28,183**
Cost of goods sold	2,019	2,037	1,955	2,125	2,477	2,989
Gross profit	9,937	7,724	9,734	10,431	32,388	25,194
Sales & Marketing	-8,837	-6,460	-7,692	-8,500	-8,800	-8,500
General & Administrative	-17,868	-16,588	-16,331	-13,881	-11,799	-8,000
Research & Development	-17,647	-18,596	-16,542	-13,600	-10,880	-8,000
Other expenses	0	-371	0	0	0	
Total operating expenses (OPEX)	**-44,352**	**-41,644**	**-40,565**	**-35,981**	**-31,479**	**-24,500**
Operating income (EBIT)	**-34,415**	**-34,291**	**-30,831**	**-25,550**	**909**	**694**
Net financial result	-13,980	-7,610	-8,420	-4,800	-4,700	-3,600
Pre-tax income (EBT)	**-48,395**	**-41,901**	**-39,251**	**-30,350**	**-3,791**	**-2,906**
Income taxes	0	0	0	0	0	0
Net income / loss	**-48,395**	**-41,901**	**-39,251**	**-30,350**	**-3,791**	**-2,906**
Minority Interests (+/-)	941	601	759	560	560	560
Net Income after minorities	**-47,454**	**-41,300**	**-38,492**	**-29,790**	**-3,231**	**-2,346**
Diluted EPS (USD)	**-36.18**	**-1.79**	**-130.69**	**-10.11**	**-0.57**	**-0.40**
Ratios						
EBIT Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of OPEX						
Sales & Marketing	19.9%	15.5%	19.0%	23.6%	n.a.	n.a.
General & Administrative	40.3%	39.8%	40.3%	38.6%	37.5%	n.a.
Research & Development	39.8%	44.7%	40.8%	37.8%	34.6%	32.7%
Y-Y Growth						
Revenue	n.a.	n.a.	19.8%	7.4%	n.a.	-19.2%
Operating income	n.a.	n.a.	n.a.	n.a.	n.a.	-23.6%
Net income/ loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in USD '000	2022	2023	2024	2025E	2026E	2027E
Assets						
Current Assets, Total	**22,321**	**27,963**	**32,198**	**29,764**	**31,117**	**31,178**
Cash and cash equivalents	5,469	6,469	8,002	5,002	5,591	4,789
Accounts receivables	2,467	2,184	1,647	1,762	1,886	2,018
Inventories	7,024	9,189	10,345	11,000	12,000	13,080
Other current assets	7,361	10,121	12,204	12,000	11,640	11,291
Non-Current Assets, Total	**25,131**	**22,800**	**21,227**	**19,516**	**17,812**	**16,146**
Property plant and equipment	557	496	464	468	477	538
Right-of-use assets	1,140	1,176	936	955	974	974
Intangible assets	22,439	20,116	18,479	16,677	14,875	13,073
Other assets	995	1,012	1,348	1,415	1,486	1,560
Total Assets	**47,452**	**50,763**	**53,425**	**49,280**	**48,929**	**47,323**
Shareholders' Equity & Debt						
Current Liabilities, Total	**30,339**	**13,987**	**19,704**	**21,864**	**20,356**	**18,532**
Accounts payable	5,808	4,974	5,286	6,608	7,929	8,008
Derivative liabilities	15,883	4,867	12,038	12,900	10,000	8,000
Other current liabilities	8,648	4,146	2,380	2,356	2,427	2,524
Longterm Liabilities, Total	**18,469**	**31,879**	**24,742**	**23,093**	**20,984**	**19,886**
Derivative liabilities	17,744	30,993	23,503	22,003	20,003	19,003
Other liabilities	725	886	1,239	1,090	981	883
Minority interests	**-699**	**-64**	**-791**	**-791**	**-791**	**-791**
Shareholders Equity	**-657**	**4,961**	**9,770**	**5,114**	**8,380**	**9,696**
Total Consolidated Equity and Debt	**47,452**	**50,763**	**53,425**	**49,280**	**48,929**	**47,323**
Ratios						
Current ratio (x)	0.74	2.00	1.63	1.36	1.53	1.68
Quick ratio (x)	0.50	1.34	1.11	0.86	0.94	0.98
Net gearing	832.4%	-130.4%	-81.9%	-97.8%	-66.7%	-49.4%
Book value per share (€)	n.a.	0.22	33.17	1.73	1.47	1.66
Net debt	-5,469	-6,469	-8,002	-5,002	-5,591	-4,789
Equity ratio	-1.4%	9.8%	18.3%	10.4%	17.1%	20.5%

CASH FLOW STATEMENT

All figures in USD '000	2022	2023	2024	2025E	2026E	2027E
Net income	**-48,395**	**-41,901**	**-39,251**	**-30,350**	**-3,791**	**-2,906**
Interest, net	13,980	7,610	8,420	4,800	4,700	3,600
Tax provision	0	0	0	0	0	0
Non-operating items	0	0	0	0	0	0
EBIT	**-34,415**	**-34,291**	**-30,831**	**-25,550**	**909**	**694**
Depreciation and amortisation	1,981	2,013	1,900	1,898	1,893	1,891
EBITDA	**-32,434**	**-32,278**	**-28,931**	**-23,652**	**2,802**	**2,585**
Derivative liability & others	11,758	13,206	274	862	-2,900	-2,000
Share based payments	3,318	2,112	1,641	1,500	1,500	800
Changes in w orking capital	-2,952	-8,119	-1,901	664	558	-761
Other adjustments	-12,794	-8,163	-467	-1,600	-600	-600
Operating cash flow	**-33,104**	**-33,242**	**-29,384**	**-22,226**	**1,360**	**25**
CapEx	-1,675	0	-231	-100	-100	-150
Free cash flow	**-34,779**	**-33,242**	**-29,615**	**-22,326**	**1,260**	**-125**
Other investments	0	0	0	0	0	0
Cash flow from investing	**-1,675**	**0**	**-231**	**-100**	**-100**	**-150**
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	20,462	33,944	31,910	20,000	0	0
Warrants Financing	0	1,236	0	0	0	
Other financing activities	2,719	-953	-708	-674	-671	-677
Cash flow from financing	**23,181**	**34,227**	**31,202**	**19,326**	**-671**	**-677**
Impact of exchange rates on cash	16	15	-54	0	0	0
Net cash flows	**-11,582**	**1,000**	**1,533**	**-3,000**	**589**	**-802**
Cash, start of the year	17,051	5,469	6,469	8,002	5,002	5,591
Cash, end of the year	**5,469**	**6,469**	**8,002**	**5,002**	**5,591**	**4,789**
Y-Y Growth						
Operating Cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	-98.2%
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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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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RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	19 May 2025	$5.88	Buy	$60.00
2	Today	$2.50	Buy	$40.00

INVESTMENT HORIZON

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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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