EDISON

Creo Medical

FY22 results

Entering phase of accelerating growth inflection

Healthcare equipment and services

FY22 was a key inflection period for Creo with significant traction in the adoption of Speedboat Inject (its flagship electrosurgical device) and its proprietary CROMA technology platform, reflected in major robotic deals with Intuitive Surgical and CMR Surgical. Total revenue growth (8% y-o-y to £27.2m) was in line with consensus (£27m) and was primarily driven by Creo's core technology business. Operating losses rose to £30.8m, affected by increased personnel and R&D expenses, although management expects a sharp reduction from FY23 following cost-optimisation measures implemented in H222. We expect further expansion of the Speedboat Inject user base (with an emphasis on training enrolment) to be the strategic priority in FY23. With the recent fund-raise of £33.7m (gross) in Q123, we estimate the company is funded to operational profitability in H126. Incorporating the improved cash balance post the reporting period, our valuation increases to £528m (150p/share) from £493m.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/21	25.2	(29.7)	(14.6)	0.0	N/A	N/A
12/22	27.2	(31.0)	(14.9)	0.0	N/A	N/A
12/23e	32.8	(24.3)	(6.3)	0.0	N/A	N/A
12/24e	40.8	(14.8)	(3.6)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Focus on broadening the product portfolio in FY23

With Speedboat Inject continuing to gain traction, Creo is planning to tap into more opportunities by expanding its product portfolio. In November 2022, the company launched Speedboat Slim, a slimmer version of Speedboat Inject, compatible with the majority of currently used endoscopes. In addition, the company submitted a 510(k) application with the US FDA for its new device, Speedboat Flush (the slimmest version of Speedboat), in February 2023. Notably, Creo commenced the first in-human and post-market study of its MicroBlate Flex device in April 2023.

Fund-raise to take Creo to operational profitability

Despite the skittish capital market situation, Creo was able to raise £33.7m (gross) in Q123 in two oversubscribed rounds of funding, signalling shareholder confidence in the company. In the first round (February 2023), the company raised £28.5m in gross proceeds (£26.8m net) through an accelerated book building process by issuing 142.5m new shares at 20p/share. Alongside this, Creo announced an open offer of £5.2m to all eligible shareholders, which was fully subscribed in March 2023. The equity raise, though dilutive in nature, provides operating capital to fund the company's growth and commercialisation plans to profitability.

Valuation: £528m or 150p per share

Our valuation increases to £528m from £493m, mainly reflecting the increased cash balance following the Q123 fund-raise, but given the increased number of shares outstanding, our per share valuation is now 150p (vs 272p). We believe funds on hand should be sufficient to take Creo to net profitability in H126.

2 May 2023

Price	**26p**
Market cap	**£92m**

Pro forma net cash (£m) at 31 December 2022 (includes £32m fund-raise in Q123)	33.4
Shares in issue	350.9m
Free float	87.8%
Code	CREO
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(15.5)	28.5	(76.1)
Rel (local)	(17.7)	27.6	(76.6)

52-week high/low: 102p / 18p

Business description

Creo Medical is a UK-based healthcare company focusing on the development and commercialisation of minimally invasive electrosurgical devices. It has six products in the flagship CROMA platform, all of which have been CE marked and four of which have been cleared by the FDA. In 2020 Creo acquired Albyn Medical, which provides it with profitable products and a direct salesforce in Europe.

Next events

Q123 trading update	May 2023

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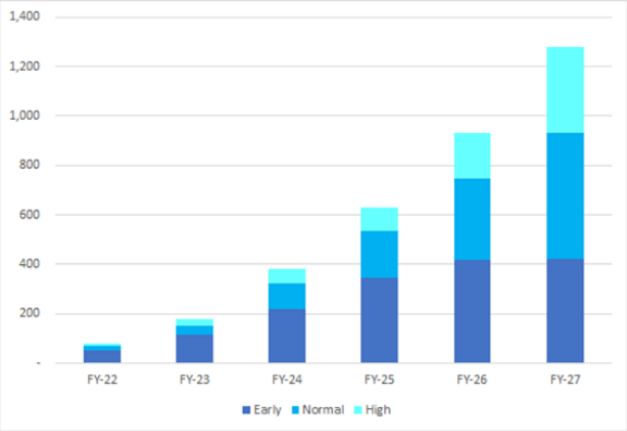
FY23 to focus on driving CROMA technology forward

Speedboat gaining market traction

FY22 was an eventful period for Creo Medical, marked by growing adoption of the company's core CROMA technology platform and its flagship Speedboat Inject device. With a year-on-year three times increase in revenue from Speedboat Inject and CROMA (£0.9m in FY22), a four times increase in user base and a robust training pipeline of clinicians (487 trainees), Creo enters FY23 with a strong foundation to scale operations and expand the scope of its CROMA technology. Reflecting this continued momentum, management has indicated that total procedures (using Speedboat Inject) in Q123 were 50% higher than the FY22 quarterly average and Q422 actual cases.

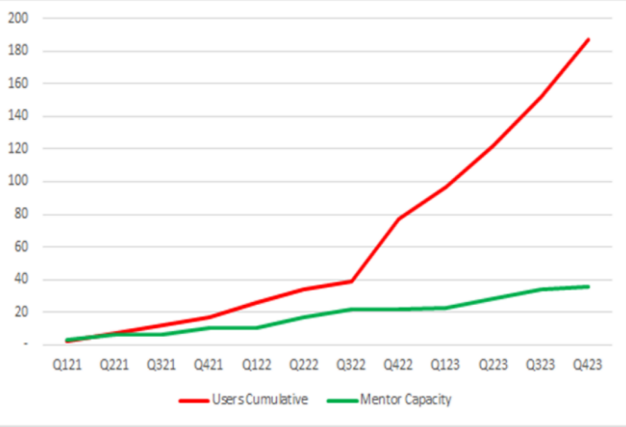
Creo reported in FY22 the total number of Speedboat users significantly increased to 80 (91 by end-March 2023) compared to 20 users in FY21. More than 1,500 procedures performed to date and 487 potential users under its clinical training programme (Pioneer) further indicate the favourable user response for the device and the near-term sales potential. Increased investment in training and mentoring capability has resulted in an enhanced user base, and Creo plans to continue its emphasis on the Pioneer training programme to sustain the momentum. The company nearly doubled the number of training centres in FY22, resulting in similar growth in the number of physicians on its training programme (450 in FY22 vs 230 in FY21). Creo has a backlog of over 90 trainees, which the company expects to convert into regular users in FY23. Additionally, Creo intends to collaborate with the American Society for Gastrointestinal Endoscopy and other key academic centres such as UCI Health, Mayo, Penn and Baylor to further extend the scope and reach of its training courses in the United States.

Exhibit 1: Creo's user forecast data by usage category



Source: Creo Medical presentation, March 2023

Exhibit 2: Creo's user and mentoring capacity



Source: Creo Medical presentation, March 2023

Building a base for other CROMA-powered devices

Along with enhancing the Speedboat user base, Creo has been focusing on developing a broader product portfolio to increase the operational scope of its offerings. As part of its portfolio expansion strategy, Creo launched a slimer version of Speedboat Inject, Speedboat Slim, in November 2022, which management says is compatible with the majority of currently used endoscopes globally, along with paediatric endoscopes, for both lower and upper gastrointestinal (GI) procedures. With initial orders already received, the company expects Speedboat Slim to contribute to FY23 revenue.

Creo submitted a 510(k) FDA application in February 2023 for Speedboat Flush, the slimmest version of Speedboat, compatible with endoscopes with a 2.8mm working channel, targeting GI lesions (including bowel and upper GI cancer) and swallowing disorders. We note that standard upper endoscopes have an external diameter in the range of 8.0–9.8mm with a 2.4–2.8mm channel. In addition to the US regulatory process, management plans for Medical Device Regulation submission for CE marking in April 2023. Creo expects that the device, after successful regulatory clearance, will be ready for clinical use in H223.

In addition, the company announced a multicentre observational study in April 2023 to assess the safety and efficacy of MicroBlate Flex, a soft tissue microwave ablation device for both liver and pancreas. We note that the device has been CE marked in Europe and received FDA clearance in January 2021. This first in-human clinical study for the device is a post-market, prospective, single-arm, multicentre, non-randomised, observational study, which plans to enrol up to 32 patients in six sites in Europe and possibly one site in the United States. During the trial, MicroBlate Flex will be used in bronchoscopic microwave ablation of peripheral lung nodules. It also requires a post-procedure assessment and six follow-up visits at seven days, 31–45 days, three months, six months, nine months and 12 months. Recruitment for the study has commenced, with the first treatment expected in Q223. The primary completion of the study (which we believe to be the date when the last patient is recruited) is anticipated in March 2024, while the full study completion is expected in March 2025. We believe these observational studies are a step forward in developing and increasing the market potential for Creo's devices. The user data, if positive, might lead to enhanced adoption of the device. We note that this post-market study is one of several planned by Creo (in collaboration with its Kamaptive technology partners) for its ablation devices in 2023.

Incremental growth opportunities in Consumables

Post its acquisition in June 2020, Albyn Medical has been an integral part of Creo's suite of products, generating stable, and the majority of, revenue (91.6% in FY22) for the company. Creo's recent announcement relating to the final earnout payment and acquisition of the remaining 5% stake in Albyn Medical (for €1.2m and an additional €1m as a second earnout tranche) is a reflection of the successful integration of and contribution from the mature business. As a reminder, Albyn Medical is a seller of own and third-party consumables and systems (primarily GI endoscopy related) with a core focus on the UK and European markets, and complements Creo's core portfolio of minimally invasive electrosurgical devices (using proprietary CROMA technology). Creo acquired a 90% stake in Albyn in July 2020 for an equity value of €24.8m and €2.7m in performance-related payments over two years. Creo then acquired another 5% stake in March 2022 (for €1.2m and an additional €1.7m as the first earnout tranche) followed by the balance in April 2023.

In order to leverage the extensive range of Albyn's endotherapy products (initially marketed only in Europe), Creo launched many of these products in the United States during FY22 as part of bundled products with its core technology. We believe this strategy will not only expand the geographic scope for these products, but will potentially create higher revenue per procedure. Management states that consumables sales in Q123 were up 10% compared to the FY22 quarterly average. As a step forward, Creo plans to use a similar strategy for the consumables launch in Asia-Pacific in FY23.

Financials

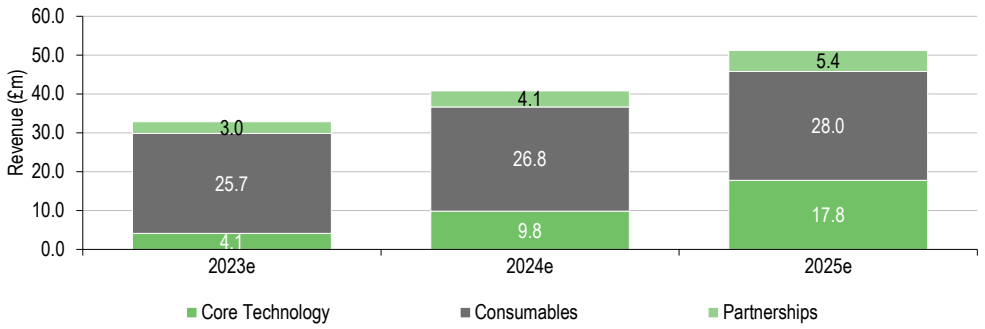
Creo reported FY22 revenue of £27.2m, an 8.0% y-o-y increase, with growth primarily driven by enhanced sales uptake of its flagship Speedboat Inject (3x growth to £0.9m in FY22 vs FY21) and initial licensing revenue of £1.4m from its existing Kamaptive technology (non-exclusive) agreements. The Consumables segment recorded largely similar revenue at £24.9m in FY22 (vs

£24.8m in FY21), however it remains the primary revenue contributor for Creo, accounting for 91.6% of total revenue. During the year, the total number of Speedboat users quadrupled to over 80 in FY22 (91 in Q123) from 20 in FY21, indicating growing market acceptance of the product and a favourable conversion rate from its training programme. Though we have limited visibility of licensing revenue, we expect Creo's core technology products (3.2% of total revenue or £0.9m in FY22) to be the key growth drivers in the medium to long term. Gross margin for the year increased from 46.0% (FY21) to 48.3%, mainly reflecting improved margins from Consumables sales and no-cost licensing deals.

The total operating loss in FY22 stood at £30.8m, higher than £29.9m in FY21, mainly attributed to increased investment in operational capacity and higher personnel expenses associated with recruitment of senior employees to support the operational growth and completion of R&D projects. Consequently, total operating expenses during the year grew 5.7% (y-o-y) to £43.9m. While sales and marketing expenses recorded a minor increase to £3.8m (FY21: £3.2m), a 4.8% growth in R&D expenses (to £13.5m) was mainly related to completion of key R&D projects in H122. Following this, operating expenses witnessed a decline of 18.7% in H222. As most of the company's products are now developed, and following the restructuring of its R&D teams, management expects this trend of decreasing operating expenses (as a percentage of sales) to continue, resulting in a year-on-year decline in overall operating expenses in FY23. In Q123, the company recorded 10% lower operating expenses compared to the FY22 quarterly average. We note that the majority of Creo's ongoing R&D programmes are funded by its licensing partners, such as Intuitive, as part of the licensing agreements. In FY22, Creo was reimbursed £4.0m, 31.4% of FY21 R&D expenditure, under the tax credit scheme. The net loss stood at £26.9m in FY22, higher than £24.6m in FY21.

Although our long-term assumptions remain unchanged for Creo, we have made minor adjustments to our FY23 estimates and have introduced FY24 forecasts. We have revised FY23 revenue estimates to £32.8m (£31.0m previously) based on Speedboat Inject user data in FY22. While we assume moderate growth of 3.4% in Consumables sales in FY23, we estimate core technology to ramp up to account for about 12% of total group revenue (vs 3% in FY22). Additionally, we anticipate income from licensing agreements in FY23. However, given limited information and visibility of the CMR deal terms, we project £3.0m of milestone income from the Intuitive agreement in FY23. We have also increased our FY23 estimate for operating expenses to £41.8m (£38.4m previously) given the trends shown in FY22, but we anticipate a year-on-year reduction (vs FY22) based on company guidance and reduced R&D spending requirements. These changes translate into an operating loss of £24.0m (£21.6m previously). In FY24, we estimate revenue at £40.8m as we expect an accelerated ramp up in core technology products, along with incremental revenues from robotics deals from the Intuitive licensing agreement. We also anticipate the Consumables segment to benefit from bundled sales in the United States and Asia-Pacific in FY24. Reflecting the impact of higher revenue and a further anticipated reduction in operating expenses (£39.1m), our operating loss estimate stands at £14.6m in FY24.

Exhibit 3: FY23–25 revenue forecasts by business area



Source: Edison Investment Research

Valuation: £528m or 150p per share

Our valuation for Creo Medical increases to £528m from £493m, mainly due to the higher cash balance resulting from the equity fund-raise of c £32.0m (£26.8m in net proceeds plus £5.2m in gross proceeds) in Q123. Given the increased number of shares outstanding, the per share valuation is now 150p per basic share (vs 272p previously).

In February 2023, Creo raised £28.5m in gross proceeds (£26.8m net) through institutional investors by placing 142.5m new ordinary shares at 20p/share (a 28% discount to the 15 February closing price). The fund-raise was oversubscribed against the minimum target of £25m, indicating strong shareholder support. In addition, the company announced an open offer to existing eligible shareholders to raise another £5.2m in funds via the conditional issue of c 26m ordinary shares, which was fully subscribed in March 2023.

Creo ended FY22 with a cash balance of £13.1m and £11.7m in debt. After incorporating the £26.8m (net proceeds) fund-raise via an accelerated book building process and £5.2m (gross proceeds) from an open offer, we estimate a pro forma net cash position of £33.4m. Based on our projected cash burn rates, we expect the current cash balance should be sufficient to take Creo to operational profitability in H126 (FY25 according to management estimates). Additionally, we expect milestone payments from the CMR deal and potential revenue from several heads of terms agreements could further strengthen the cash flow. These have been excluded from our current estimates due to limited visibility.

Exhibit 4: Creo's valuation

Product	Main indication	Status	Probability of successful commercialisation	2027 sales (£m)	rNPV (£m)
Core Technology (Croma Platform)	GI, soft tissues and pulmonology	Market	100%	48	385.5
Consumables (Albyn Medical)	Urology, gynaecology and GI	Market	100%	32	75.5
Partnerships (Intuitive)			50%		33.7
Total					494.6
Estimated net cash (31 December 2022) including January fund-raise					33.4
Total firm value					**528.0**
Total basic shares (m)					350.9
Value per basic share (£)					**1.50**
Options (m)					0.0
Total number of shares (m)					350.9
Diluted value per share (£)					1.50

Source: Edison Investment Research

Exhibit 5: Financial summary

£'000s	2021	2022	2023e	2024e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	25,161	27,169	32,817	40,754
Cost of Sales	(13,576)	(14,047)	(15,015)	(16,321)
Gross Profit	11,585	13,122	17,802	24,433
Research & Development Expenses	(12,869)	(13,492)	(11,468)	(9,175)
Sales, General & Administrative expenses	(25,490)	(27,325)	(27,052)	(26,781)
EBITDA	(19,982)	(20,805)	(20,667)	(11,472)
Underlying EBITDA (Adjusted for R&D tax credit)	(14,238)	(16,764)	(17,027)	(9,249)
Operating profit (before amort. and excepts.)	(29,284)	(30,756)	(23,954)	(14,642)
Intangible Amortisation	0	0	0	0
Other	52	51	51	51
Exceptionals	(623)	0	0	0
Operating Profit	(29,907)	(30,756)	(23,954)	(14,642)
Net Interest	(432)	(221)	(313)	(179)
Other	0	0	0	0
Profit Before Tax (norm)	(29,716)	(30,977)	(24,267)	(14,820)
Profit Before Tax (reported)	(30,339)	(30,977)	(24,267)	(14,820)
Tax	5,744	4,041	3,640	2,223
Deferred tax	0	0	0	0
Profit After Tax (norm)	(23,972)	(26,936)	(20,627)	(12,597)
Profit After Tax (reported)	(24,595)	(26,936)	(20,627)	(12,597)
Average Number of Shares Outstanding (m)	164.4	181.3	329.7	350.9
EPS - normalised (p)	(14.58)	(14.85)	(6.26)	(3.59)
EPS - Reported (£)	(0.15)	(0.15)	(0.06)	(0.04)
Dividend per share (£)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	39,442	41,650	41,002	39,962
Intangible Assets	27,255	27,643	26,752	25,896
Tangible Assets	8,603	10,184	10,427	10,242
Other	3,584	3,823	3,823	3,823
Current Assets	61,167	33,687	43,754	33,520
Stocks	8,504	9,325	9,968	10,835
Debtors	4,830	6,765	8,171	10,148
Cash	43,534	13,097	17,475	2,174
Other	4,299	4,500	8,140	10,363
Current Liabilities	19,737	17,483	15,100	15,937
Creditors	9,921	9,000	9,620	10,457
Short term borrowings	5,381	5,616	2,613	2,613
Other short-term liabilities	4,435	2,867	2,867	2,867
Long Term Liabilities	7,554	8,451	7,425	6,399
Long term borrowings	5,175	6,067	5,041	4,015
Other long term liabilities	2,379	2,384	2,384	2,384
Net Assets	73,318	49,403	62,230	51,145
CASH FLOW				
Operating Cash Flow	(23,199)	(24,955)	(17,002)	(9,743)
Net Interest	(463)	(287)	(326)	(196)
Tax	(2,349)	258	(3,640)	(2,223)
Capex	(6,122)	(3,274)	(2,638)	(2,130)
Acquisitions/disposals	(1,752)	(2,753)	0	0
Financing	34,208	0	32,000	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	323	(31,011)	8,394	(14,292)
Opening net debt/(cash)	(32,737)	(32,978)	(1,414)	(9,821)
HP finance leases initiated	0	0	0	0
Exchange rate movements	(303)	(56)	0	0
Other	221	(497)	13	17
Closing net debt/(cash)	(32,978)	(1,414)	(9,821)	4,454

Source: company reports, Edison Investment Research

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