Elbit Medical Technologies

Development update

Gamida hits on Phase III

Pharma & biotech

Elbit Medical's holding Gamida Cell recently reported data from its 125-patient Phase III study of omidubicel in patients with haematological malignancies undergoing bone marrow transplants. The median time to neutrophil engraftment was 12 days for omidubicel patients compared to 22 days for those receiving standard umbilical cord blood (p<0.001). Gamida Cell expects to initiate the rolling biologic licence application (BLA) submission in Q420 and launch in 2021.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/18	35.0	26.8	0.12	0.0	N/A	N/A
12/19	16.8	(21.2)	(0.09)	0.0	N/A	N/A

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

Omidubicel Phase III data positive

Gamida Cell reported data from its 125-patient Phase III study of omidubicel in patients with haematological malignancies undergoing bone marrow transplants. The median time to neutrophil engraftment was 12 days for omidubicel patients compared to 22 days for those receiving standard umbilical cord blood (p<0.001). Additionally, among patients who were transplanted per protocol, 96% of those who received omidubicel achieved successful neutrophil engraftment, compared to 88% of those receiving standard umbilical cord blood.

Gamida raises $69m in gross proceeds

Following the positive Phase III data, Gamida Cell made an offering of 15.3m shares at $4.50 per share for a total of $69m in gross proceeds. The company estimates that it is now fully funded into H221. Additionally, Elbit Medical sold 312,000 shares of Gamida in May and continue to hold approximately 2.4m shares of the company Following the stock sales and the dilution from the offering, Elbit Medical's fully diluted stake in Gamida Cell has been reduced from approximately 7% to 4.1%.

Cash boost from InSightec stake sale

The successful sale of most of its InSightec stake provided Elbit with $102.2m in cash. The company used part of the proceeds in Q120 to repurchase 133.3m shares for $38m and will use most of the remainder of the cash for either the payment or repurchase of debt.

Valuation: NIS208.5 or NIS2.12 per share

We have reduced our valuation from NIS229.7m or NIS2.34 per share to NIS208.5m or NIS2.12 per share. This is mainly due to a reduction in net cash as well as a change in the value of the Gamida stake, which decreased due to both the dilution from the Gamida offering and Elbit Medical selling a portion of its stake. The reduction in the value of the Gamida offering was partially offset by an increase in the probability of success for omidubicel from 50% to 70% following the Phase III data.

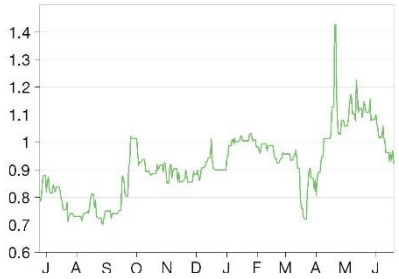
23 June 2020

Price*	**NIS0.92**
Market cap	**NIS91m**

*Priced at 19 June 2020

	NIS3.50/US$
Net cash ($m) at 31 March 2020 + Gamida sale + debt repurchase	16.4
Shares in issue	98.1m
Free float	65%
Code	EMTC
Primary exchange	TASE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(17.4)	27.0	11.1
Rel (local)	(15.8)	6.8	17.0

52-week high/low	NIS1.4	NIS0.7

Business description

Elbit Medical Technologies is an Israeli biomedical and healthcare technology group. Its portfolio of two companies is focused on medical devices and therapeutics: InSightec, which develops and markets the ExAblate platform for non-invasive thermal tissue ablation, and Gamida Cell, which is developing a universal bone marrow transplant.

Next events

Rolling BLA submission for omidubicel	Q420

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Edison profile page

Positive omidubicel Phase III data

Positive data were recently reported for Gamida Cell's 125-patient Phase III study of omidubicel in patients with haematological malignancies. The median time to neutrophil engraftment was 12 days for omidubicel patients compared to 22 days for those receiving standard umbilical cord blood ($p<0.001$). Additionally, among patients who were transplanted per protocol, 96% of those who received omidubicel achieved successful neutrophil engraftment, compared to 88% of those receiving standard umbilical cord blood.

As a reminder, omidubicel, which is this company's lead asset, expands umbilical cord blood (UCB) cell grafts ex vivo and enriches the specific subpopulation of stem and progenitor cells to treat haematological malignancies such as leukaemia and lymphoma. Essentially, CD133+ cells selected from a single unit of UCB are cultured for approximately three weeks in nicotinamide and are then cryopreserved until they are transplanted into the intended patients. This expansion of stem and progenitor cells is expected to provide a substantial advantage over a single UCB graft. The use of UCB for bone marrow transplantation (BMT) is generally limited by the minimal number of stem and progenitor cells. By expanding these cells, the omidubicel process seeks to provide a more viable alternative to BMT in cancer patients and only partial genetic matching is needed (ie a minimum requirement of four out of six human leukocyte antigen biomarkers). The registrational trial investigated the ability of omidubicel to provide a graft with an ample number of cells that have fast and vigorous in vivo neutrophil- and platelet-producing potential to improve transplantation outcomes (as low UCB cell dose is associated with delayed engraftment and poor outcomes). Gamida Cell expects to initiate the rolling BLA submission in Q420 and launch in 2021.

Gamida Cell ended Q120 with $40.3m in cash and marketable securities. In May, following the release of the Phase III data, Gamida Cell completed an offering of 15.3m shares (including the underwriters' overallotment options) at $4.50 per share for a total of $69m in gross proceeds. Gamida Cell has guided for a $60–70m cash outflow for operating activities in 2020 and expects its current resources (following the offering) to fund its operations into H221 Following the stock sales and the dilution from the offering, Elbit Medical's fully diluted stake in Gamida Cell has been reduced from approximately 7% to 4.1%.

Valuation

We have reduced our valuation from NIS229.7m or NIS2.34 per share to NIS208.5m or NIS2.12 per share. This is mainly due to a reduction in net cash as well a change in the value of the Gamida stake, which decreased due to both the dilution from the Gamida offering and Elbit Medical selling a portion of its stake. The reduction in the value of the Gamida offering was partially offset by an increase in the probability of success for omidubicel from 50% to 70% following the Phase III data.

Exhibit 1: Elbit Medical valuation table

Product	Setting	Status	Launch	Peak sales ($m)	Probability of success	Royalty rate	rNPV ($m)	% owned by Elbit Medical (fully diluted)	Elbit Medical rNPV ($m)
InSightec	MRgFUS (for gynaecology, oncology, neurology indications)	Market	Market	583	100%	100%	723	2.8%	20.2
Gamida Cell	Leukemia (AML, ALL, CML, CLL)	Phase III	2021	370	70%	100%	547	4.1%	22.4
Portfolio total ($m)									42.7
Net cash (as of 31 March 2020 + net proceeds of Gamida share sale + debt repurchase) ($m)									16.4
Overall valuation									59.1
Shekel/dollar conversion rate									3.5
Overall valuation in shekels (NISm)									208.5
Shares outstanding (m)									98.1
Per share (NIS)									2.12

Source: Edison Investment Research, Elbit Medical Technologies

Financials

Elbit Medical recently announced its Q120 financial results. Net income was $118.5m, mainly due to profits stemming from the sale of its InSightec stake. General and admin costs for the period were $0.3m, which includes management fees, professional services and other related expenses. The company had cash, cash equivalents, short-term deposits and restricted cash of $62.2m at 31 March 2020 and $47.8m in debt (which includes $1.6m in fair value for the bond conversion component). Since the end of the quarter, the company raised $2m by selling part of its stake in Gamida Cell and in June it repurchased debt with NIS1.9m par value for NIS2.3m. We outline historical financials in Exhibit 2. Please note we continue not to provide financial forecasts at this time.

Exhibit 2: Financial summary

US$'000s	2018	2019
Year end 31 December	IFRS	IFRS
PROFIT & LOSS		
Revenue	34,951	16,803
Cost of Sales	0	0
Gross Profit	34,951	16,803
R&D expenses	0	0
SG&A expenses	(918)	(470)
Other expenses	0	(15,937)
EBITDA	34,033	396
Operating Profit (before amort. and except.)	34,033	396
Intangible Amortisation	0	0
Exceptionals	0	0
Operating Profit	34,033	396
Other	0	(14,847)
Net Interest	(7,212)	(6,769)
Profit Before Tax (norm)	26,821	(21,220)
Profit Before Tax (FRS 3)	26,821	(21,220)
Tax	0	0
Profit After Tax (norm)	26,821	(21,220)
Profit After Tax (FRS 3)	26,821	(21,220)
Average Number of Shares Outstanding (m)	231.5	231.5
EPS - normalised ($)	0.12	(0.09)
EPS - FRS 3 ($)	0.12	(0.09)
Dividend per share ($)	0.0	0.0
BALANCE SHEET		
Fixed Assets	24,233	11,548
Intangible Assets	23,016	11,548
Tangible Assets	0	0
Other	1,217	0
Current Assets	3,797	2,248
Stocks	0	0
Debtors	11	35
Cash	3,786	2,213
Other	0	0
Current Liabilities	(1,526)	(1,522)
Creditors	(1,526)	(1,522)
Short term borrowings	0	0
Short term leases	0	0
Other	0	0
Long Term Liabilities	(41,998)	(48,961)
Long term borrowings	(39,030)	(46,661)
Long term leases	0	0
Other long-term liabilities	(2,968)	(2,300)
Net Assets	(15,494)	(36,687)
CASH FLOW		
Operating Cash Flow	(499)	(571)
Tax	0	0
Capex	0	0
Acquisitions/disposals	0	0
Financing	0	0
Dividends	0	0
Other	(4,113)	2,165
Net Cash Flow	(4,612)	1,594
Opening net debt/(cash)	42,383	35,244
HP finance leases initiated	(6,835)	(2,542)
Other	18,586	(8,256)
Closing net debt/(cash)	35,244	44,448

Source: Company accounts

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