EDISON

Elbit Medical Technologies

Clinical update

Another FDA approval and a US IPO

Pharma & biotech

Elbit Medical Technologies' two portfolio investments continue to advance. Notably, Gamida Cell announced a $53m IPO on Nasdaq in late October and presented NiCord data at the American Society of Hematology (ASH) annual meeting in December. InSightec reported record revenues for Q318 and received FDA approval for ExAblate Neuro compatibility with Siemens' magnetic resonance (MR) scanners.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/15	1.8	(1.1)	(0.0)	0.0	N/A	N/A
12/16	0.0	(3.7)	(0.0)	0.0	N/A	N/A
12/17	0.0	(5.2)	(0.0)	0.0	N/A	N/A

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

InSightec's ExAblate Neuro compatible with Siemens

InSightec (~22% owned by Elbit Medical, ~18.5% fully diluted) recently announced its Q318 results. Revenues, which are based on the sale of ExAblate systems and corresponding annual service contract costs and consumables, were $8.1m, up 105% from Q217 ($4.0m). Notably, InSightec announced that it had received FDA approval for ExAblate Neuro compatibility with Siemens' MR scanners. We expect this will provide InSightec with the opportunity to expand its presence in the global MR market.

Gamida Cell IPOs on NASDAQ

Gamida Cell recently announced a $53m IPO on Nasdaq under the symbol GMDA, for 6.25m ordinary shares at $8.00 per share. Following this offering, Elbit Medical now owns ~11% of the company (previously ~18%). Gamida Cell also presented an update regarding its Phase I/II of NiCord as a graft evaluating immune reconstitution (IR) after myeloablative chemotherapy versus non-manipulated cord blood and traditional unrelated bone marrow transplant at ASH.

Elbit Imaging sells shares in Elbit Medical

On 6 September, Elbit Imaging sold approximately 5% of Elbit Medical's outstanding share capital to Exigent Capital Group for NIS11.1m. Two months later, Elbit Imaging sold an additional 10% of Elbit Medical's outstanding share capital to the group for NIS21.3m. According to reports from 21 November and 28 November, Elbit Imaging sold an additional 8% and 3% of Elbit Medical's outstanding share capital for NIS18.6m and NIS6.7m, respectively. Following these transactions, Elbit Imaging now owns ~63% of Elbit Medical (previously ~89%). The proceeds from these transactions will be used to repay their debts.

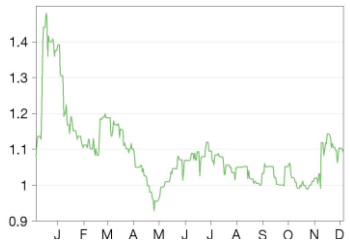
Valuation: NIS424m or NIS1.83 per share

We are decreasing our valuation to NIS424m NIS1.83 per share from NIS444.4m or NIS1.92 per share, which was mainly driven by the decrease in value of Elbit Medical's stake in Gamida Cell following the IPO and offset by the increase in strength of the US dollar (NIS3.69/US$). We expect to update our valuation with the announcement of new deals and as the portfolio companies advance through the clinical pipeline.

6 December 2018

Price	**NIS1.10**
Market cap	**NIS254m**
Priced as at 6 December 2018	
	NIS3.69/US$
Net debt ($m) at 30 June 2018	38.7
Shares in issue	231.5m
Free float	25.3%
Code	EMTC
Primary exchange	TASE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	8.4	3.5	(2.2)
Rel (local)	6.5	2.6	(12.2)
52-week high/low	NIS1.5	NIS0.9	

Business description

Elbit Medical Technologies (Elbit Medical), a fully controlled subsidiary of Elbit Imaging (EMITF), 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

Gamida Cell NiCord Phase III top-line data	H120
InSightec Parkinson's disease Phase II/III top-line data	2020

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Edison profile page

Record revenues, new reimbursement and an approval

On 1 October 2018, InSightec announced that it received FDA approval for ExAblate Neuro compatibility with Siemens Healthineers' Magnetom Skyra, Prisma, and Prisma^{fit} clinical MR scanners for the treatment of essential tremor (ET). We expect this will provide InSightec with the opportunity to expand its presence in the global MR market. In November, the company announced that Medicare had updated the reimbursement code for MRgFUS ET to $12,500.50 (previously $17,500.50). Pain palliation will be reimbursed at $10,936.00. These will take effect as of 1 January 2019, although it is unclear what impact this will have on sales.

As a reminder, the ExAblate system compromises magnetic resonance imaging and high-intensity focused ultrasound (MRgFUS) to perform non-invasive thermal tissue ablation for a wide range of neurology, oncology and gynaecology clinical applications. By way of full clinical validation under the pre-market approval route, the company has achieved FDA approval and CE markings for the ExAblate 2100 system for the treatment of symptomatic uterine fibroids and pain palliation caused by bone metastases, and for its ExAblate 4000 system for the treatment of medication-refractory ET. Moreover, the company has received CE markings for the treatment of prostate cancer, tremor-dominant Parkinson's disease and neuropathic pain, and is investigating these further in clinical trials in an effort to achieve FDA approval.

With regard to the underlying business, InSightec recently reported its Q318 financials. Revenues, which are based on the sale of ExAblate systems and corresponding annual service contract costs and consumables, were $8.1m, which more than doubled from Q217 ($3.9m). R&D expenses totalled $7.4m for the period, which reflects ongoing clinical development. The company is targeting FDA approval for the use of its ExAblate technology for the treatment of prostate cancer and tremor-dominant Parkinson's disease in 2020 and 2021, respectively. Furthermore, Elbit Medical recently announced that the FDA has given InSightec the green light to initiate a clinical trial investigating the use of MRgFUS for targeted drug delivery for Alzheimer's disease.

Gamida Cell's IPO on Nasdaq and NiCord data at ASH

On 26 October 2018, Gamida Cell announced the listing of its IPO on NASDAQ under the symbol GMDA, having offered 6,250,000 ordinary shares at $8.00 per share, totalling $53m (including the underwriters' option to purchase up to an additional 937,500 ordinary shares at the IPO price). BMO Capital Markets and RBC Capital Markets acted as joint book-running managers for the offering, while Needham & Company and Oppenheimer acted as co-lead managers. Following the offering, Elbit Medical's ownership of Gamida Cell has decreased to ~11% (from ~18%).

Moreover, Gamida Cell presented translational data from its Phase I/II study of NiCord as a graft after myeloablative chemotherapy at the ASH Annual meeting on 1 December 2018. Overall, 27 (median age 41.5 years) out of 36 patients had evaluable blood samples for early monitoring of immune reconstitution (IR). Delayed IR following cord blood transplantation is associated with significant morbidity (ie increased risks of infections, relapse, development of secondary malignancies) and mortality.[1, 2] IR is affected by human leukocyte antigen (HLA) discrepancy between donor and host, graft versus host disease (GvHD), preparative radiation/chemotherapy

1 M. R. M. Van Den Brink, Velardi, E., & Perales, M. (2015). Immune reconstitution following stem cell transplantation. Hematology,2015(1), 215-219.

2 Komanduri, K. V., et al. (2007). Delayed immune reconstitution after cord blood transplantation is characterized by impaired thymopoiesis and late memory T-cell skewing. Blood,110(13), 4543-4551.

regimens and age-related thymic involution.[3] Data from this cohort were compared to subgroups of patients with hematologic malignancies receiving non-manipulated cord blood transplantation (n=27, median age 15.4 years) and T-cell-replete, unrelated bone marrow transplantation (n=20, median age 14.3 years). Ninety-one percent of the patients achieved the primary end point, which was defined as successful CD4+ IR (>50×106/L) within the first 100 days following NiCord transplantation. No difference in probability of early CD4+ IR was noted between the groups (p=0.76). The secondary end points were IR of CD4+ and CD8+ T-Cells, natural killer (NK) cells, B-cells and monocytes during the first year after transplantation. The study found that IR of T-cells were similar among the groups, while IR of NK cells (p<0.001) and B-cells (p=0.02) after NiCord transplantation was faster in comparison to the other groups.

Furthermore, on 4 December 2018, Gamida Cell published the complete data set from its Phase I/II NiCord study in all 36 patients with high-risk haematological malignancies in the Journal of Clinical Oncology. The primary end points of the trial were the cumulative incidence of neutrophil engraftment at 42 days (with ≤10% host cells) and the incidence of secondary graft failure. NiCord and the Center for International Blood and Marrow Transplant Research (CIBMTR) historical comparator cohort demonstrated a cumulative incidence of neutrophil engraftment at 42 days post-transplantation of 94% and 85%, respectively, and neutrophil engraftment was faster in NiCord recipients (p<0.001). Of the patients who engrafted, median time to neutrophil recovery was 11.5 days and 21 days for the NiCord and CIBMTR comparator cohort, respectively. Platelet engraftment was also faster in NiCord recipients (p<0.001), and for those who achieved platelet recovery, median time to platelet recovery 34 days for NiCord recipients and 46 days for the CIBMTR matched cohort. One NiCord patient experienced primary graft failure, while two NiCord recipients experienced secondary graft failure (at day 19 and day 262). The cumulative incidence of grade II through grade IV acute graft-versus-host disease at day 100 was 44% and 56% for NiCord recipient and the matched cohort, respectively. These data indicate that NiCord has the potential to be the graft of choice for patients without a matched donor; however, it is important to note that the study included a retrospective cohort of patients and the NiCord cohort had a relatively small sample size. We expect the Phase III trial, which is expected to be fully enrolled in H219, to elucidate the findings presented in this study.

Exhibit 1: Investment portfolio

Investment	Technology	% held	Founded	Status	Advantages	Targets
InSightec	MRgFUS to treat various indications with thermal tissue ablation	~22% (~18.5% fully diluted)	1999	ExAblate (Body): FDA and CE approved for uterine fibroids and pain palliation due to bone metastases. ExAblate (Neuro): FDA and CE approved for unilateral thalamotomy in the treatment of essential tremor.	Provides non-invasive alternatives to common standard procedures and improves patient outcomes by minimizing recovery time. InSightec's ExAblate system is the only MRgFUS therapy with CE and FDA approval.	Evaluating potential for bilateral thalamotomy in the treatment of essential tremor with ExAblate Neuro device. Enrolment is underway for Phase III study of ExAblate Neuro to treat Parkinson's disease.
Gamida Cell	Cord stem cell transplant for hematologic diseases	~11%	1998	NiCord: Enrolling Phase III; CordIn: Two ongoing Phase I/II trials; natural killer cells: Initiated Phase I.	UCB for transplantation only requires partial matching and nicotinamide technology increases the limited population and quality of stem and progenitor cells. NiCord received FDA breakthrough therapy designation.	Enrolment for a Phase III study of NiCord expected to be complete in H219.

Source: Elbit Medical Technologies

3 Lucchini, G., Perales, M., & Veys, P. (2015). Immune reconstitution after cord blood transplantation: Peculiarities, clinical implications and management strategies. Cytotherapy,17(6), 711-722.

Valuation

We are decreasing our valuation to NIS424m NIS1.83 per share from NIS444.4m or NIS1.92 per share. This change was driven by the decrease in value of Elbit Medical's stake in Gamida Cell following the IPO and offset by the increase in strength of the US dollar (NIS3.69/US$). We expect to update our valuation with the announcement of new deals and as the portfolio companies advance through the clinical pipeline.

Exhibit 2: Valuation of Elbit Medical

Product	Setting	Status	Launch	Peak sales ($m)	Probability of success	Royalty rate	rNPV ($m)	% owned by Elbit Medical (fully diluted)	Elbit Medical rNPV ($m)
InSightec	MRgFUS (for gynaecology, oncology, neurology indications)	Market	Market	583	100%	100%	579	18.5%	107.2
Gamida Cell	Leukaemia (AML, ALL, CML, CLL)	Phase III	2020	437	50%	100%	423	11%	46.5
Portfolio total ($m)									153.7
Net debt (as at 30 June 2018) ($m)									38.7
Overall valuation									115.0
Shekel/dollar conversion rate									3.7
Overall valuation in shekels (NISm)									424.3
Shares outstanding (m)									231.5
Per share (NIS)									1.83

Source: Edison Investment Research

Financials

Elbit Medical reports financials in six-month increments. Its H118 post-tax gain was $2.1m (H117 post-tax loss: $7.1m), mainly from financing income. General and admin costs for the period were $0.59m (NIS2.1m), which include management fees, professional services, as well as other related expenses. The company had cash on the balance sheet of $1.7m (NIS6.2m) at 30 June 2018. Elbit Medical completed an NIS180m offering of convertible notes (NIS1.47 par value in notes convertible to one Elbit Medical ordinary share) on the TASE in February 2018, as well as an NIS2m offering of Series C convertible notes (NIS2.1 par value of notes convertible to Elbit Imaging) in March 2018, which lengthens the maturity profile to March 2022. The company used the majority of the proceeds to repay its NIS154m debt to Elbit Imaging earlier this year, while NIS4m was set aside for ongoing operational expenses, in addition to approximately NIS18m set aside for interest payments due on the notes for the first two years. The notes are secured by a lien on the company's holdings in InSightec and Gamida Cell, which therefore introduces significant dilution risk to Elbit Medical shareholders.

We outline historical financials in Exhibit 3. However, we are not providing forecasts at this time.

Exhibit 3: Financial summary

US$000s	2015	2016	2017
Year-end 31 December	IFRS	IFRS	IFRS
PROFIT & LOSS			
Revenue	1,752	0	0
Cost of Sales	0	0	0
Gross Profit	1,752	0	0
R&D expenses	0	0	0
SG&A expenses	0	(553)	(677)
EBITDA	1,174	(553)	(677)
Operating Profit (before amort. and except.)	1,174	(553)	(677)
Intangible Amortisation	0	0	0
Exceptionals	(14,428)	(15,000)	(5,518)
Operating Profit	(13,254)	(15,553)	(6,195)
Other	(2,270)	(3,101)	(4,557)
Net Interest	0	0	0
Profit Before Tax (norm)	(1,096)	(3,654)	(5,234)
Profit Before Tax (FRS 3)	(15,524)	(18,654)	(10,752)
Tax	0	0	0
Profit After Tax (norm)	(1,096)	(3,654)	(5,234)
Profit After Tax (FRS 3)	(15,524)	(18,654)	(10,752)
Average Number of Shares Outstanding (m)	1,851.9	1,851.9	1,851.9
EPS - normalised (c)	(0.00)	(0.00)	(0.00)
EPS - FRS 3 (US$)	(0.01)	(0.01)	(0.01)
Dividend per share (c)	0.0	0.0	0.0
BALANCE SHEET			
Fixed Assets	20,520	5,518	50
Intangible Assets	0	0	0
Tangible Assets	0	0	0
Other	20,520	5,518	50
Current Assets	103	30	40
Stocks	0	0	0
Debtors	6	15	8
Cash	97	15	32
Other	0	0	0
Current Liabilities	(131)	(57)	(60)
Creditors	(131)	(57)	(60)
Short term borrowings	0	0	0
Short term leases	0	0	0
Other	0	0	0
Long Term Liabilities	(33,873)	(37,126)	(42,415)
Long term borrowings	(33,873)	(37,126)	(42,415)
Long term leases	0	0	0
Other long term liabilities	0	0	0
Net Assets	(13,381)	(31,635)	(42,385)
CASH FLOW			
Operating Cash Flow	(2,531)	(3,394)	(4,858)
Tax	0	0	0
Capex	0	0	0
Acquisitions/disposals	0	0	0
Financing	0	0	0
Dividends	0	0	0
Other	3	0	0
Net Cash Flow	(2,528)	(3,394)	(4,858)
Opening net debt/(cash)	31,248	33,776	37,111
HP finance leases initiated	0	0	0
Other	0	59	(414)
Closing net debt/(cash)	33,776	37,111	42,383

Source: Company reports, Edison Investment Research

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