EDISON

Elbit Medical Technologies

Financial update

Full-year financial results

Pharma & biotech

Elbit Medical Technologies' two portfolio investments continue to advance on multiple fronts. InSightec recently completed its compatibility project with Siemens MR scanners and its ExAblate Neuro units, which lends the opportunity to expand its presence in the global MR market. According to Gamida Cell, its cash balance should fund its operations through the top-line readout of its Phase III study of NiCord, which is expected in H120.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/16	0.0	(3.7)	(0.00)	0.0	N/A	N/A
12/17	0.0	(5.2)	(0.00)	0.0	N/A	N/A
12/18	23.0	3.8	0.12	0.0	N/A	N/A

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

InSightec completes Siemens compatibility project

In December, InSightec (~22% owned by Elbit Medical, ~18% fully diluted) announced the receipt of FDA-expanded approval of ExAblate Neuro for the treatment of tremor-dominant Parkinson's disease (PD). Notably, InSightec received the both FDA approval and CE mark for ExAblate Neuro compatibility with Siemens magnetic resonance (MR) scanners and we expect this to provide InSightec with the opportunity to expand its presence in the global MR market.

Gamida Cell looks to 2019 and 2020

Gamida Cell (~11% owned by Elbit Medical, ~8% fully diluted) has set clear milestones for the next few years. According to the company, its current cash position of $60.7m will provide a runway through March 2020, which is roughly in line with company expectations for delivering top-line NiCord data. Provided that these Phase III data are positive, Gamida Cell plans to submit a BLA filing for NiCord for the treatment of haematological malignancies in H220.

Elbit Imaging sells shares in Elbit Medical

Elbit Imaging recently entered into another share purchase agreement with Exigent Capital Group for the sale of between 1.6% and 25% of the ordinary shares of Elbit Medical for a price per share of NIS0.96 on or before 27 March 2019. Additionally, Exigent Capital may purchase up to 25% of shares through 13 May 2019 for a price per share of NIS1.02. As of 28 March 2019, 1.6% of Elbit Medical's outstanding share capital was sold for NIS3.6m. Since August 2018, Elbit Imaging has sold roughly 27.6% of Elbit Medical's outstanding share capital to Exigent Capital. Therefore, Elbit Imaging owns ~61.6% of Elbit Medical.

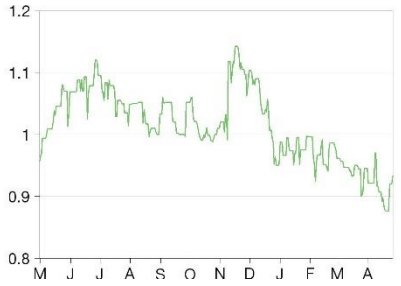
Valuation: NIS507.4m or NIS2.19 per share

We have increased our valuation to NIS507.4m or NIS2.19 per share, from NIS424m or NIS1.83 per share, primarily attributed to increasing the potential market share of ExAblate Neuro systems to include the opportunity of installing units on Siemens MR scanners. These changes were partially offset by the decrease of Elbit Medical's stake (fully diluted) in Gamida Cell following its IPO.

30 April 2019

Price	**NIS0.93**
Market cap	**NIS215m**
Priced at 26 April 2019	
	NIS3.62/US$
Net debt ($m) at 31 December 2018	34.0
Shares in issue	231.5m
Free float	10.7%
Code	EMTC
Primary exchange	TASE
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	3.3	(4.3)	(2.4)
Rel (local)	(1.7)	(10.5)	(12.5)
52-week high/low	NIS1.1	NIS0.9	

Business description

Elbit Medical Technologies, a fully controlled subsidiary of Elbit Imaging, 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

Expanded MR compatibility with Siemens

The ExAblate system comprises 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 (PMA) route, the company has achieved FDA approval and CE markings for the ExAblate 2100 (Body) system for the treatment of symptomatic uterine fibroids and pain palliation caused by bone metastases, and for its ExAblate 4000 (Neuro) system for the treatment of medication-refractory ET (essential tremor). Moreover, the company has received CE markings for the treatment of prostate cancer, neuropathic pain and tremor-dominant PD. InSightec is investigating these devices further in clinical trials to achieve FDA approval and, on 18 December 2018, announced the FDA approved an expansion of ExAblate Neuro to include the treatment of patients with medication-refractory tremor-dominant PD. In February 2019, InSightec announced that Noridian posted positive local coverage determination for MRgFUS effective 1 April 2019 and that Medicare beneficiaries in 38 US states will have coverage for the treatment of ET using MRgFUS.

The clinical presence of the ExAblate platform is limited by the number of compatible MRI systems installed in hospital settings. We therefore believe the recent completion of the compatibility project for ExAblate Neuro with Siemens Magnetom Aera 1.5T and Skyra 3T clinical MR scanners in the US and in Europe could potentially double the accessible global MRI market for ExAblate Neuro. According to the Organisation for Economic Co-operation and Development, as of 2016 there were more than 5,400 MRI units active in US hospitals (roughly 16.67 per one million of the US population).[1] This numeric excludes MRI units installed in outpatient imaging centres as we assume MRgFUS procedures will require the presence of a specialized surgeon. According to EvaluateMedTech, the diagnostic medical imaging market is led by Siemens Healthineers, GE Healthcare and Philips with 26%, 21% and 19% of the market share in 2016, respectively. Currently, the ExAblate Body systems are exclusively compatible with GE Healthcare's 1.5 and 3.0 Tesla MR scanners.

Disrupting the BBB using MRgFUS

On 30 January 2019, InSightec announced that the first patient completed temozolomide (TMZ) chemotherapy cycles in a clinical trial investigating the safety and efficacy MRgFUS for disrupting the blood brain barrier (BBB) in patients with glioblastoma. Gliomas are a collection of malignant tumours arising from glia or glial precursor cells within the central nervous system that form in the brain and spinal cord.[2] Glioblastoma, also known as glioblastoma multiforme (GBM), is the most aggressive of the gliomas and affects less than 10 per 100,000 people in the US.[2] Despite treatment (ie surgery to remove the tumour and adjuvant chemo- or radiation therapy) the disease is largely incurable and most patients with GBM have a median survival of about 14 to 15 months.[3] Also, cytotoxic therapies such as chemotherapy do not effectively cross the BBB. The trial, which is being conducted at the University of Maryland Medical System in the US, is expected to enrol 15 patients with GBM and will analyse the number and severity of device and procedure related adverse events and investigate the feasibility of BBB disruption at the time of the procedure and 24 hours post-procedure.

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1 OECD (2018), Magnetic resonance imaging (MRI) units (indicator).

2 Holland, E. C. (2000). Glioblastoma multiforme: The terminator. Proceedings of the National Academy of Sciences, 97(12), 6242-6244.

3 Hanif, F., et al. (2017). Glioblastoma Multiforme: A Review of its Epidemiology and Pathogenesis through Clinical Presentation and Treatment. *Asian Pacific Journal of Cancer Prevention* : APJCP, 18(1), 3–9.

Regarding the underlying business, InSightec recently reported its FY18 financials. Revenues, which are based on the sale of ExAblate systems and corresponding annual service contract costs and consumables, were $38.0m, up from $32.1m in FY17. R&D expenses totalled $28.4m for the year, which reflects ongoing clinical development.

Gamida Cell sets clear milestones for 2019–20

Gamida Cell's 120-patient Phase III study of NiCord in patients with haematological malignancies is ongoing. NiCord, which is the company's lead asset, expands umbilical cord blood (UCB) cell graft 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 21 days in nicotinamide resulting in a c 100-fold expansion of dose stem and progenitor cells, which are then cryopreserved until they are transplanted into patients. This expansion is expected to provide a substantial advantage over a single UCB graft. The registrational trial is investigating the ability of NiCord 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 cell dose is associated with delayed engraftment and poor outcomes). The primary endpoint for the trial is time to neutrophil engraftment following transplantation (on or before the 42nd day post-transplant) compared to a non-manipulated cord blood unit. The use of UCB for bone marrow transplantation (BMT) is limited by the minimal number of stem and progenitor cells. The NiCord 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 HLA biomarkers). Enrolment is on track for completion in H219 with top-line data expected in H120. Provided that these Phase III data are positive, Gamida Cell plans to submit a BLA filing for NiCord for the treatment of haematological malignancies in H220.

The company is also investigating NiCord for the treatment of severe aplastic anaemia (SAA) in an ongoing Phase I/II study. Gamida Cell recently presented data on three patients included in the first cohort (Exhibit 1) with SAA and severe neutropenia who previously failed immunosuppressive therapy at the annual Transplantation & Cellular Therapy (TCT) Meetings of American Society for Blood and Marrow Transplantation and Center for International Blood and Marrow Transplant Research in Houston in February 2019.

Exhibit 1: NiCord Phase I/II study design in SAA

Cohort	No. patients	Notes
1	Three to six	Single NiCord-expanded unit combined with 3 x 10^6 CD34+ cells/kg from a haploidentical donor as a stem cell backup
2	Up to 20	Once adequate cord engraftment is established* transplant with NiCord-expanded unit alone

Source: Gamida Cell. Notes: Patients conditioned with cyclophosphamide (60mg/kg x 2), horse ATG (40mg/kg x 4), fludarabine (25 mg/m^2 x 5), and 200cGy of TBI and graft-versus-host-disease prophylaxis with tacrolimus and MMF. *Defined as three of the first three to four patients, four of six patients with ANC>500 cells/µl by day 29 and cord ANC >500 cells/µl by day 42 sustained at day 100. ANC: absolute neutrophil count.

From 2017 to 2018, three SAA patients (age/gender: 22 male, 45 female, 22 female), who all previously failed immunosuppressive therapy, with a pre-transplant absolute neutrophil count (ANC) ≤ 500 cells/µl, successfully underwent a single 5/8 or 6/8 HLA-matched NiCord-expanded UCBT (UCB transplant) combined with haploidentical CD34+ cells from a haploidentical donor as a stem cell backup. For the three NiCord-expanded transplants, the median time to neutrophil and platelet recovery was six days (range six to seven) and 31 days (range 15–40), respectively. All three patients achieved cord engraftment (ANC>500 cells/µl) at a median of six days, which was sustained at day 100. Moreover, these patients were alive and free of graft-versus-host-disease at a median follow-up of 11 months (range four to 18 months). It is important to note these findings are based on only a small number of patients and significant variability between subjects was observed.

According to the company, patient inclusion in cohort one is complete, and it expects to proceed with cohort two to evaluate engraftment and transplantation outcomes with the NiCord-expanded unit alone (in other words, without a haploidentical donor) in 20 patients with SAA.

NAM-NK cells

Gamida Cell is also developing donor-derived natural killer (NK) cells for blood and solid cancers. NK cells are a type of lymphocyte, or white blood cell, that play a central role in lysing infected or transformed cells and therefore offer an innovative approach to cancer treatment. The company previously initiated a 24-patient Phase I trial with the University of Minnesota evaluating the safety and activity of nicotinamide (NAM)-NK cells in patients with Non-Hodgkin's lymphomas and multiple myeloma (MM). In February, preliminary data from 14 patients (Exhibit 2) were presented at the TCT annual meeting.

Exhibit 2: Patient and disease characteristics

Disease	No. of patients (n=14)
MM	8
Follicular lymphoma	3
Transformed lymphoma	2
DLBCL	1
Disease status	
Relapsed	10
Refractory	4

Source: Gamida Cell

The objective of this Phase I study is to determine the maximum tolerated dose of NAM-NK. NAM-NK was generally well tolerated with no dose-limiting toxicities or infusion toxicity. However, several grade 3/4 hematologic toxicities were observed as well as low-grade non-haematological toxicities. The maximum target dose (MTD) of $2x10^8$ cells/kg were achieved. Some clinical activity was observed in six patients with lymphomas and an additional six patients with MM who were evaluable for response (Exhibit 3). The trial remains ongoing and additional patients will be treated at the MTD to continue to evaluate safety and clinical activity. Gamida Cell expects to initiate a multi-centre Phase I/II study of NAM-NK in patients with blood cancers in 2020.

Exhibit 3: Clinical activity observed in 12 evaluable patients

Disease	No. of patients	Clinical response
Non-Hodgkin's lymphomas (n=6)	3	CR
	1	PR
	2	PD
MM (n=6)	1	CR
	2	SD
	3	PD

Source: Gamida Cell. Notes: CR: complete response; PR: partial response; PD: progressive disease; SD: stable disease.

Also in February 2019, Gamida Cell announced an agreement with Editas Medicine, a genome-editing company, to evaluate the potential use of its CRISPR technology to edit Gamida's NAM-NK cells. The two companies will engage in joint research focused on improving the tumour-killing properties of NAM-NK cells with CRISPR editing technology.

Gamida Cell (NASDAQ: GMDA, market capitalisation of $210m) recently reported its full-year financial results. The company reported a post-tax loss of $52.9m in FY18. R&D expenditure was $22.0m for FY18, which is up roughly 47% from FY17 ($15.0m), primarily attributed to the increase in clinical activities related to the advancement of the NiCord Phase III clinical programme in haematological malignancies and the initiation of the NAM-NK clinical programme. R&D spending is expected to increase substantially as the company advances its product candidates through clinical development. According to Gamida Cell, its cash position of $60.7m (including cash and equivalents, available-for-sale financial assets and short-term deposits) at 31 December 2018 will

provide a runway through March 2020, which is roughly in line with company expectations for delivering top-line NiCord data. The company foresees the need for significant financing in the future.

Exhibit 4: Investment portfolio

Investment	Technology	% held	Founded	Status	Advantages	Targets
InSightec	MRgFUS to treat various indications with thermal tissue ablation	~22% (~18% 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 and of tremor-dominant PD.	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 PD.
Gamida Cell	Cord stem cell transplant for hematologic diseases	~11% (~8% fully diluted)	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 underway for a Phase III study of NiCord and on track for completion in H219 with top-line results expected in H120 and BLA filing in H220.

Source: Elbit Medical Technologies

Valuation

We have increased our valuation of Elbit Medical Technologies to NIS507.4m or NIS2.19 per share, from NIS424m or NIS1.83 per share. These changes are primarily driven by increasing the potential market share of ExAblate Neuro systems to include the possibility of installing units on Siemens MR scanners. Previously, both the ExAblate Neuro and Body systems were exclusively compatible with GE Healthcare's MR scanners. The completion of the compatibility project with Siemens provides InSightec with the opportunity to expand its presence in the global MR market and increase the number of active ExAblate units. This change in overall valuation was also compounded by rolling forward our NPVs and the slightly lower net debt. These changes were partially offset by the decrease in strength of the US dollar (NIS3.62/US$), the decrease of Elbit Medical's stake (fully diluted) in Gamida Cell following its October 2018 IPO, and the slight decrease of Elbit Medical's stake (fully diluted) in InSightec.

Exhibit 5: Valuation of Elbit Medical Technologies

Product	Setting	Status	Launch	Peak sales ($m)	Probability of success	Royalty rate	rNPV ($m)	% owned by Elbit Medical (fully diluted)	Elbit Medical rNPV ($m)
InSightec	MRgFUS (for gynaecology, oncology, neurology indications)	Market	Market	903	100%	100%	756	18%	136.0
Gamida cell	Leukaemia (AML, ALL, CML, CLL)	Phase III	2020	437	50%	100%	477	8%	38.2
Portfolio total ($m)									174.2
Net debt (as of 31 December 2018) ($m)									(34.0)
Overall valuation ($m)									140.2
Shekel/dollar conversion rate									3.6
Overall valuation in shekels (NISm)									**507.4**
Shares outstanding (m)									231.5
Per share (NIS)									**2.19**

Source: Company reports, Edison Investment Research

Financials

Elbit Medical recently announced its full-year 2018 financial results. Its FY18 post-tax gain was $26.8m, mainly from its reduced stake in Gamida Cell following its IPO. General and admin costs for the year were $0.9m, which includes management fees, professional services and other related expenses. The company had cash of $5m (including cash and equivalents as well as restricted cash) at 31 December 2018 and $39.0m in debt. We outline historical financials in Exhibit 6. However, we are not providing forecasts at this time.

Exhibit 6: Financial summary

US$'000s	2016	2017	2018
Year end 31 December	IFRS	IFRS	IFRS
PROFIT & LOSS			
Revenue	0	0	23,016
Cost of Sales	0	0	0
Gross Profit	0	0	23,016
R&D expenses	0	0	0
SG&A expenses	(553)	(677)	(918)
EBITDA	(553)	(677)	22,098
Operating Profit (before amort. and except.)	(553)	(677)	22,098
Intangible Amortisation	0	0	0
Exceptionals	(15,000)	(5,518)	0
Operating Profit	(15,553)	(6,195)	22,098
Other	(3,101)	(4,557)	4,723
Net Interest	0	0	0
Profit Before Tax (norm)	(3,654)	(5,234)	3,805
Profit Before Tax (FRS 3)	(18,654)	(10,752)	26,821
Tax	0	0	0
Profit After Tax (norm)	(3,654)	(5,234)	3,805
Profit After Tax (FRS 3)	(18,654)	(10,752)	26,821
Average Number of Shares Outstanding (m)	1,851.9	1,851.9	231.5
EPS - normalised (c)	(0.00)	(0.00)	0.12
EPS - FRS 3 (USD)	(0.01)	(0.01)	0.12
Dividend per share (c)	0.0	0.0	0.0
BALANCE SHEET			
Fixed Assets	5,518	50	24,233
Intangible Assets	0	0	23,016
Tangible Assets	0	0	0
Other	5,518	50	1,217
Current Assets	30	40	3,797
Stocks	0	0	0
Debtors	15	8	11
Cash	15	32	3,786
Other	0	0	0
Current Liabilities	(57)	(60)	(1,526)
Creditors	(57)	(60)	(1,526)
Short term borrowings	0	0	0
Short term leases	0	0	0
Other	0	0	0
Long Term Liabilities	(37,126)	(42,415)	(41,998)
Long term borrowings	(37,126)	(42,415)	(39,030)
Long term leases	0	0	0
Other long term liabilities	0	0	(2,968)
Net Assets	(31,635)	(42,385)	(15,494)
CASH FLOW			
Operating Cash Flow	(3,394)	(4,858)	4,533
Tax	0	0	0
Capex	0	0	0
Acquisitions/disposals	0	0	0
Financing	0	0	0
Dividends	0	0	0
Other	0	0	0
Net Cash Flow	(3,394)	(4,858)	4,533
Opening net debt/(cash)	33,776	37,111	42,383
HP finance leases initiated	0	0	0
Other	59	(414)	2,606
Closing net debt/(cash)	37,111	42,383	35,244

Source: Company reports, Edison Investment Research

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