Elbit Medical Technologies

Financial update

H119 results

Pharma & biotech

Elbit Medical Technologies' two portfolio investments continue to make progress. InSightec recently received both FDA approval and a CE mark for ExAblate Neuro compatible with the SIGNA Premier MRI system from GE Healthcare as the two companies work on improving incisionless brain surgery. Gamida Cell recently completed a $40m follow-on offering and expects to complete enrolment of the Phase III for NiCord (now called omidubicel) by the end of the year, with data 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	35.0	26.8	0.12	0.0	N/A	N/A

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

Gamida Cell getting closer to data

Gamida Cell (~8% owned by Elbit Medical, ~7% fully diluted) is on track to complete enrolment for its Phase III trial of NiCord (now called omidubicel) in hematological malignancies by the end of 2019 (previously H219) with topline data expected in H120. If these Phase III data are positive, Gamida Cell plans to submit a biologic license application (BLA) filing for omidubicel in H220. The current cash runway is enough to fund operations into Q420.

Another set of approvals for InSightec

In July, InSightec announced it received both FDA approval and a CE mark for ExAblate Neuro compatible with the SIGNA Premier MRI system from GE Healthcare as the two companies work on improving incisionless brain surgery.

InSightec sales grew 19% in Q219

Revenues, which are based on the sale of ExAblate systems and corresponding annual service contract costs and consumables, were $9.0m in Q219, up 19% from the $7.5m in Q218. This is a deceleration from the 31% growth seen in Q1. For the first half as a whole, sales were $15.1m, up 24%.

Valuation: NIS353.1m or NIS1.53 per share

We have decreased our valuation from NIS507.4m or NIS2.19 per share, to NIS353.1m or NIS1.53 per share, mainly because InSightec sales have not been progressing as fast as expected (we have reduced peak sales from $647m to $583m, still assuming strong growth from current levels) and also due to the dilution of Elbit Medical's stake in Gamida Cell following the secondary offering (from 8% to 7%). We have also delayed omidubicel's launch from 2020 to 2021 to be a bit more conservative on timing. Additionally, net debt has increased since our previous note.

25 September 2019

Price*	**NIS0.92**
Market cap	**NIS213m**

*Priced as at 23 September 2019

	NIS3.51/US$
Net debt ($m) at 30 June 2019	40.8
Shares in issue	231.5m
Free float	36.2
Code	EMTC
Primary exchange	TASE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	25.9	14.3	(8.2)
Rel (local)	21.0	10.2	(9.1)
52-week high/low	NIS1.1		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

Gamida Cell omidubicel Phase III top-line data	H120

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Edison profile page

Gamida Cell Phase III to complete enrolment by YE19

Gamida Cell's 120-patient Phase III study of omidubicel (formerly NiCord) in patients with hematological malignancies is ongoing. Omidubicel, 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 hematological malignancies such as leukemia and lymphoma. Essentially, CD133+ cells selected from a single unit of UCB are cultured for approximately three weeks in nicotinamide, which are then cryopreserved until they are transplanted into the intended patients. This expansion is expected to provide a substantial advantage over a single UCB graft. The use of UCB for bone marrow transplantation (BMT) is limited by the minimal number of stem and progenitor 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 is investigating 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 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 an unmanipulated cord blood unit. Enrolment is on track for completion by year end with top-line data expected in H120. Provided that these Phase III data are positive, Gamida Cell plans to submit a BLA filing for omidubicel for the treatment of hematological malignancies in H220.

The company is also investigating omidubicel for the treatment of severe aplastic anemia (SAA) in an ongoing Phase I/II study. With patient inclusion in cohort one complete (and encouraging data presented on those first cohort patients at the annual Transplantation and Cellular Therapy meeting earlier this year), enrolment into cohort two began in June. Cohort two will evaluate engraftment and transplantation outcomes with the omidubicel-expanded unit alone (in other words, without a haploidentical donor).

Gamida Cell is also developing donor-derived natural killer (NK) cells for blood cancers in its GDA-201 program. 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-NK cells in patients with non-Hodgkin's lymphoma and multiple myeloma with additional data expected by the end of the year. The company is working on a cryopreserved version of GDA-201 to enable a multi-centre, multi-dose study in non-Hodgkin's lymphoma patients in 2020.

The company ended Q219 with $37.1m in cash and raised $40.3m in gross proceeds in July. Gamida Cell has guided for a $35–40m in cash outflow for operating activities over 2019 and expects its current resources to fund its operations into Q420.

Additional approvals for InSightec

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 gynecology 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) medication-refractory tremor-dominant Parkinson's

disease (PD). Moreover, the company has received CE markings for the treatment of prostate cancer, neuropathic pain and tremor-dominant PD.

So far this year has been a busy one for the company. 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. In June, the company announced that it received national reimbursement from the Japanese Ministry of Health, Labour and Welfare (MHLW) for treating essential tremor. And most recently, in July, it announced it received both FDA approval and a CE mark for ExAblate Neuro compatible with the SIGNA Premier MRI system from GE Healthcare.

InSightec recently reported its Q219 financials. Revenues, which are based on the sale of ExAblate systems and corresponding annual service contract costs and consumables, were $9.0m in Q219, up 19% from the $7.5m in Q218. This is a deceleration from the 31% growth seen in Q1. For the first half as a whole, sales were $15.1m, up 24% from H118. Cash flow for operating activities in the first half was a negative $26.0m and the company has $10.6m in cash, indicating a near-term fundraise may be needed, which will likely dilute Elbit's share in the company. However, Elbit announced in September that InSightec is conducting early-stage negotiations with one or more investors which would include the acquisition by those investors of a significant portion of the stakes of existing investors, including Elbit Medical's, and an additional investment into InSightec at a higher valuation than the previous round ($460m pre-money, $610m post-money fully diluted).

Valuation

We have decreased our valuation from NIS507.4m or NIS2.19 per share, to NIS353.1m or NIS1.53 per share, mainly because InSightec sales have not been progressing as fast as expected (we have reduced peak sales from $647m to $583m, still assuming strong growth from current levels) and also due to the dilution of Elbit Medical's stake in Gamida Cell following the secondary offering (from 8% to 7%). We have also delayed omidubicel's launch from 2020 to 2021 to be a bit more conservative on timing. Additionally, net debt increased to $40.8m since our previous note ($34.0m). Please note that we may need to amend our valuation in the coming months if a sale of a significant portion of Elbit Medical's stake in InSightec is successfully negotiated.

Exhibit 1: 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 ($m)
InSightec	MRgFUS (for gynecology, oncology, neurology indications)	Market	Market	583	100%	100%	648	18.0%	116.6
Gamida cell	Leukemia (AML, ALL, CML, CLL)	Phase III	2021	370	50%	100%	346	7%	24.2
Portfolio total ($m)									140.8
Net cash/(debt) (as of 30 June 2019) ($m)									(40.8)
Overall valuation									100.0
Shekel/dollar conversion rate									3.5
Overall valuation in shekels (NISm)									353.1
Shares outstanding (m)									231.5
Per share (NIS)									1.53

Source: Elbit Medical Technologies reports, Edison Investment Research

Financials

Elbit Medical recently announced its H119 financial results. The post-tax loss was $14.7m, mainly due to changes in the fair value of assets and financial instruments. General and admin costs for the period were $0.2m, which includes management fees, professional services and other related

expenses. The company had cash, cash equivalents and restricted cash of $3.9m at 30 June 2019 and $44.7m in debt. We outline historical financials in Exhibit 2. Note that with the H119 results, the company has changed how it characterizes certain aspects of its income statement and has restated 2018 results, although everything below the PBT line is identical to what it was previously. Please also note that we continue not to provide forward-looking financial forecasts at this time.

Exhibit 2: Financial summary

US$000s	2016	2017	2018
Year end 31 December	IFRS	IFRS	IFRS
PROFIT & LOSS			
Revenue	0	0	34,951
Cost of Sales	0	0	0
Gross Profit	0	0	34,951
R&D expenses	0	0	0
SG&A expenses	(553)	(677)	(918)
EBITDA	(553)	(677)	34,033
Operating Profit (before amort. and except.)	(553)	(677)	34,033
Intangible Amortization	0	0	0
Exceptionals	(15,000)	(5,518)	0
Operating Profit	(15,553)	(6,195)	34,033
Other	(3,101)	(4,557)	0
Net Interest	0	0	(7,212)
Profit Before Tax (norm)	(3,654)	(5,234)	26,821
Profit Before Tax (FRS 3)	(18,654)	(10,752)	26,821
Tax	0	0	0
Profit After Tax (norm)	(3,654)	(5,234)	26,821
Profit After Tax (FRS 3)	(18,654)	(10,752)	26,821
Average Number of Shares Outstanding (m)	1,851.9	1,851.9	231.5
EPS - normalized ($)	(0.00)	(0.00)	0.12
EPS - FRS 3 ($)	(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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