EDISON

Elbit Medical

Financial update

Selling most of its InSightec stake

Pharma & biotech

Elbit Medical recently signed an agreement to sell most of its stake in InSightec for $102m at a $702m valuation for the company, leaving Elbit Medical with approximately 4.7% of InSightec (the company estimates approximately 3.7% on a fully diluted basis). At the end of Q319, Elbit Medical owned 22% of InSightec and 18% on a fully diluted basis. Completion of the transaction is subject to Elbit Medical shareholder approval and other conditions. The company expects to use the proceeds of this transaction to repay its debt, fund corporate expenses and use the remaining cash from the transaction to buy back stock through a tender offer.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
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 normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Positive GDA-201 data for Gamida Cell

Gamida Cell (~8% owned by Elbit Medical, ~7% fully diluted) recently presented data from its Phase I trial of GDA-201 in 22 heavily pre-treated non-Hodgkin lymphoma (NHL) and multiple myeloma (MM) patients at the American Society of Hematology Annual Meeting (ASH). Within the nine evaluable NHL patients, GDA-201 achieved a 56% complete response rate and a 67% objective response rate. Among the 12 evaluable MM patients, there was an 8% complete response rate while 42% achieved stable disease.

Phase III trial for omidubicel complete

Gamida Cell has completed enrolment in its Phase III trial of omidubicel in haematological malignancies with top-line data expected in H120. If these Phase III data are positive, Gamida Cell plans to submit a biologic licence application (BLA) filing for omidubicel in H220.

An eventful 2019 for InSightec

In February 2019, InSightec announced that Noridian posted positive local coverage determination for magnetic resonance imaging and high-intensity focused ultrasound (MRgFUS) and Medicare beneficiaries in 38 US states will have coverage for the treatment of essential tremor (ET) using MRgFUS. In June, the company announced it received national reimbursement in Japan for treating ET. 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.

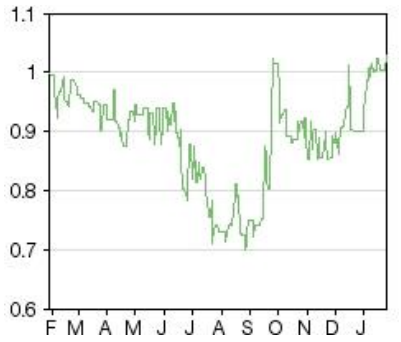
Valuation: NIS346.1m or NIS1.50 per share

We have decreased our valuation from NIS353.1m or NIS1.53 per share to NIS346.1m or NIS1.50 per share mainly due to higher net debt. A key valuation inflection point for the stake in Gamida Cell will be the Phase III data for omidubicel, expected in H120.

28 January 2020

Price	**NIS1.03**
Market cap	**NIS238m**
Priced at 24 January 2020	
	NIS3.48/US$
Net debt ($m) at 30 September 2019	42.8
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	10.8	13.3	5.6
Rel (local)	7.8	7.3	(12.2)
52-week high/low	NIS1.03		NIS0.70

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

Clinical progress for Gamida Cell

Gamida Cell recently presented data from its Phase I trial of GDA-201 in 22 heavily pre-treated NHL and MM patients at the annual ASH meeting. As a reminder, the GDA-201 programme is based on donor-derived natural killer (NK) cells. 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.

Of the 22 patients in the trial, 21 were evaluable (nine with NHL and 12 with MM). Within the evaluable NHL patients, GDA-201 achieved a 56% complete response rate and a 67% objective response rate (as there was one partial response in addition to the complete responses). Among the evaluable MM patients, there was an 8% complete response rate while 42% achieved stable disease. The company is working on a cryopreserved version of GDA-201 to enable a multi-centre, multi-dose study in NHL patients in 2020.

Additionally, Gamida Cell's 120-patient Phase III study of omidubicel in patients with haematological malignancies has completed enrolment. Omidubicel, which is the 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 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. Top-line data from the Phase IIII trial are expected in H120. Provided these Phase III data are positive, Gamida Cell plans to submit a BLA filing for omidubicel for the treatment of haematological malignancies in H220.

The company is also investigating omidubicel for the treatment of severe aplastic anaemia 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).

The company ended Q319 with $68.1m in cash and marketable securities. 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.

InSightec

The ExAblate system uses 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 (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 and 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.

Last year was busy for the company. In February 2019, InSightec announced 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 it received national reimbursement from the Japanese Ministry of Health, Labour and Welfare for treating ET. And 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 Q319 results. Revenues, which are based on the sale of ExAblate systems and corresponding annual service contract costs and consumables, were $7.3m in Q319, down 10% from $8.1m in Q318. For the first nine months, revenues were $22.4m, up 10% from the same period a year ago. Cash flow for operating activities in the first nine months was a negative $40.0m. Cash, cash equivalents and deposits totalled $66.0m as of 30 September 2019.

In late December 2019, Elbit Medical announced it has agreed to sell most of its stake in InSightec for $102m at a $702m valuation for the company, leaving Elbit Medical with approximately 4.7% of InSightec (the company estimates approximately 3.7% on a fully diluted basis). As of the end of Q319, Elbit Medical owned 22% of InSightec and 18% on a fully diluted basis. Completion of the transaction is subject to Elbit Medical shareholder approval, among other conditions. The company expects to use the proceeds of this transaction to repay its debt, fund corporate expenses and use the remaining cash from the transaction to buy back stock through a tender offer. Note that as the transaction has not yet been completed, we are not changing our estimates at this time. Elbit Medical has also announced that InSightec has executed a non-binding term sheet for an additional $100m to $150m investment from an existing InSightec shareholder, which could have an impact on our estimates as well. Elbit Medical currently estimates that if the third party investment is made that its stake in InSightec would fall from 4.7% to 3.1%.

Valuation

We have decreased our valuation from NIS353.1m or NIS1.53 per share to NIS346.1m or NIS1.50 per share mainly due to higher net debt. A key valuation inflection point for the stake in Gamida Cell will be the Phase III data for omidubicel, expected in H120. Once the InSightec transaction closes we will review our valuation as the company is selling its stake at a $702m valuation, which represents a premium to the $648m valuation for the company that we have in our model. However, this will depend on whether InSightec finalizes the $100-$150m financing from a third party and the size of Elbit Medical's remaining stake on a fully diluted basis if such a financing occurs.

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 ($m)
InSightec	MRgFUS (for gynaecology, oncology, neurology indications)	Market	Market	583	100%	100%	648	18.0%	116.6
Gamida cell	Leukaemia (AML, ALL, CML, CLL)	Phase III	2021	370	50%	100%	346	7%	24.2
Portfolio total ($m)									140.8
Net debt (at 30 September 2019) ($m)									-42.8
Overall valuation									98.0
Shekel/dollar conversion rate									3.5
Overall valuation in shekels (NISm)									346.1
Shares outstanding (m)									231.5
Per share (NIS)									1.50

Source: Elbit Medical Technologies reports, Edison Investment Research

Financials

Elbit Medical recently announced its Q319 financial results. The post-tax loss was $4.7m, mainly due to changes in the fair value of assets and financial instruments. General and admin costs for the period were $0.1m, which includes management fees, professional services and other related expenses. The company had cash, cash equivalents and restricted cash of $2.4m at 30 September 2019 and $45.2m in debt. As stated earlier, Elbit expects to pay down its debt with the proceeds of the InSightec transaction and buy back shares with the remaining cash. 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	2017	2018
Year end 31 December	IFRS	IFRS
PROFIT & LOSS		
Revenue	0	34,951
Cost of Sales	0	0
Gross Profit	0	34,951
R&D expenses	0	0
SG&A expenses	(677)	(918)
EBITDA	(677)	34,033
Operating Profit (before amort. and except.)	(677)	34,033
Intangible Amortisation	0	0
Exceptionals	(5,518)	0
Operating Profit	(6,195)	34,033
Other	(4,557)	0
Net Interest	0	(7,212)
Profit Before Tax (norm)	(5,234)	26,821
Profit Before Tax (FRS 3)	(10,752)	26,821
Tax	0	0
Profit After Tax (norm)	(5,234)	26,821
Profit After Tax (FRS 3)	(10,752)	26,821
Average Number of Shares Outstanding (m)	1,851.9	231.5
EPS - normalised (c)	(0.00)	0.12
EPS - FRS 3 (USD)	(0.01)	0.12
Dividend per share (c)	0.0	0.0
BALANCE SHEET		
Fixed Assets	50	24,233
Intangible Assets	0	23,016
Tangible Assets	0	0
Other	50	1,217
Current Assets	40	3,797
Stocks	0	0
Debtors	8	11
Cash	32	3,786
Other	0	0
Current Liabilities	(60)	(1,526)
Creditors	(60)	(1,526)
Short term borrowings	0	0
Short term leases	0	0
Other	0	0
Long Term Liabilities	(42,415)	(41,998)
Long term borrowings	(42,415)	(39,030)
Long term leases	0	0
Other long term liabilities	0	(2,968)
Net Assets	(42,385)	(15,494)
CASH FLOW		
Operating Cash Flow	(4,858)	4,533
Tax	0	0
Capex	0	0
Acquisitions/disposals	0	0
Financing	0	0
Dividends	0	0
Other	0	0
Net Cash Flow	(4,858)	4,533
Opening net debt/(cash)	37,111	42,383
HP finance leases initiated	0	0
Other	(414)	2,606
Closing net debt/(cash)	42,383	35,244

Source: Company reports

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