EDISON

Intec Pharma

Earnings update

Phase III more than half the way there

Pharma & biotech

The year 2017 was marked by steady progress in Intec's development program of AP-CDLD for the treatment of Parkinson's disease (PD). The drug is a co-formulation of widely used carbidopa and levodopa using the company's proprietary accordion pill (AP) technology. The program is in Phase III with more than 300 (of 420) patients enrolled to date with full enrolment expected in H218.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/16	0.0	(13.4)	(1.17)	0.0	N/A	N/A
12/17	0.0	(29.1)	(1.65)	0.0	N/A	N/A
12/18e	0.0	(23.6)	(0.86)	0.0	N/A	N/A
12/19e	0.0	(17.4)	(0.60)	0.0	N/A	N/A

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

Gastroscopy substudy complete

In the YE17 announcement, the company stated it completed the required gastroscopy safety substudy being performed on the first 100 patients in the Phase III trial. This substudy was previously cited as being partly responsible for the high level of withdrawals from the trial, which prompted an enrolment expansion from 328 to 420. Enrolment is expected to be complete in H218 (Q318 previously).

New pharmacokinetic study on deck

The company also announced it will be performing an additional pharmacokinetic (PK) study comparing AP-CDLD dosed three times a day to the equivalent dose of Sinemet (a branded immediate release carbidopa/levodopa) five times a day. The goal of the study is to show that AP-CDLD provides more consistent exposure to the drugs, which would in theory limit off time and dyskinesia. The results from this study will be presented in H218.

New plan for AP cannabinoids

The company previously demonstrated in a Phase I study that its AP coformulation of cannabidiol and tetrahydrocannabinol (AP-CBD/THC) showed improved exposure to both molecules compared to Sativex, although the improvement in THC exposure was marginal (25-50% improved). The company then aimed to develop a new AP formulation with improved results. Intec has stated that it intends to develop two separate formulations for each molecule, both of which should be entering Phase I in H218.

Valuation: NIS597m ($174m) or NIS22.91 ($6.68)

We have slightly decreased our valuation to NIS597m ($174m) or NIS22.91 ($6.68) per basic share from NIS619m ($176m) or NIS23.85 ($6.79) per basic share. This is driven by lower net cash ($55.2m), and offset by advancing our NPVs. Otherwise our assumptions remain unchanged. The company reported operating losses of $29.2m, which was above our expectations ($23.6m), although we still believe it will not need additional capital before profitability in 2020.

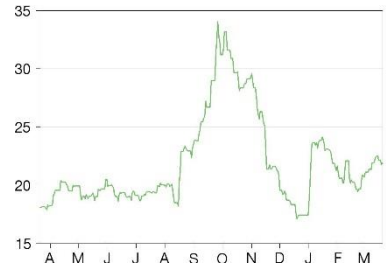
22 March 2018

Price*	**NIS21.94**
Market cap	**NIS573m**
	NIS3.42/US$

*Priced at 20 March 2018

Net cash ($m) at 31 December 2017	55.2
Shares in issue	26.1m
Free float	78%
Code	NTEC
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance



%	1m	3m	12m
Abs	11.7	27.0	20.9
Rel (local)	12.8	25.8	13.8
52-week high/low	NIS34.1		NIS17.1

Business description

Intec Pharma is a drug delivery company that has developed the accordion pill, a novel gastroretentive controlled release formulation. The company is using this technology to develop AP-CDLD for Parkinson's disease (in Phase III) and AP formulations of cannabinoids (Phase I for pain indications).

Next events

AP-CDLD TID PK study results	H218
AP-CDLD Phase III enrolment complete	H218
Cannabinoid PK studies initiate	H218

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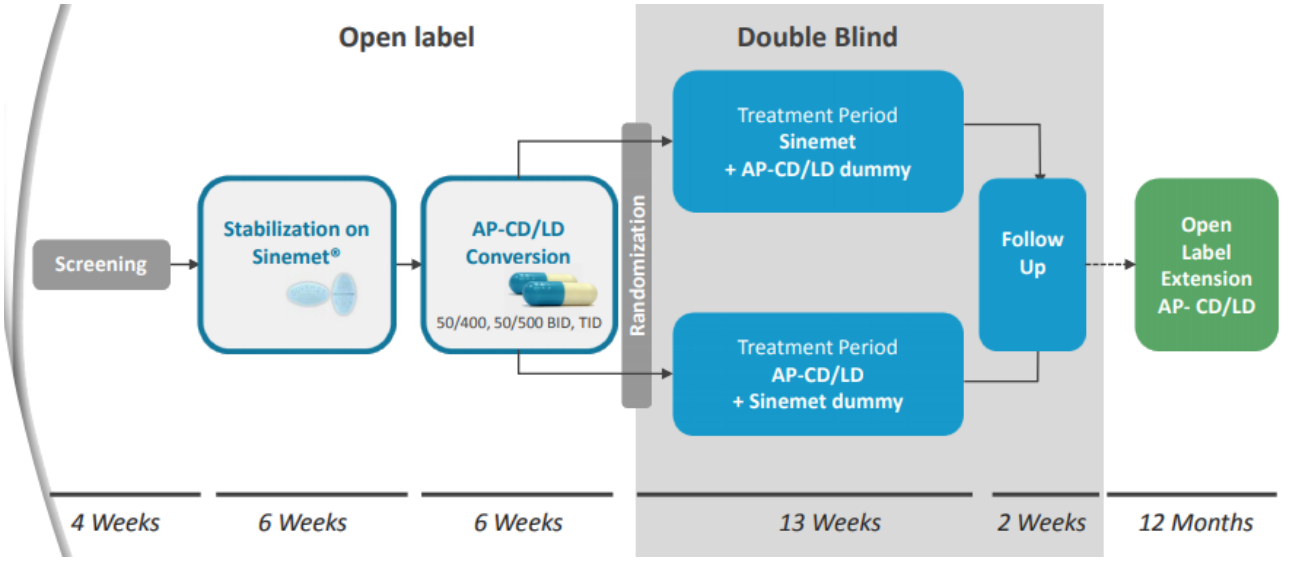
Edison profile page

A year of progress on AP-CDLD development

The year 2017 saw steady progress for Intec. The primary focus of the company has been the advancement of its Phase III program examining AP-CDLD for the treatment of PD. AP-CDLD is a formulation of carbidopa and levodopa using the company's proprietary accordion pill technology. These drugs are widely used for the treatment of symptoms associated with PD, but their utility has historically been limited by frequent dosing and poor PK. The goal of the program is to use the AP technology to provide a steady release of these drugs and avoid the frequent off periods associated with underdosing and the dyskinesia associated with overdosing.

The Phase III study has a number of design features to address some of the complexities in treating patients with carbidopa and levodopa and maintain blinding (Exhibit 1). The trial will compare AP-CDLD to Sinemet, a brand of immediate release carbidopa-levodopa. Dosing of these drugs is highly patient specific, so all participants are required to undergo two six-week dose optimisation periods for Sinemet and AP-CDLD respectively. Patients will then be randomised into the blinded portion of the study, but to maintain blinding, will receive both active and dummy pills. In patients with severe disease, we expect this to be a very high pill burden. The primary endpoint of the study is a change in daily off time from baseline, with an important secondary outcome measure of change in 'on time without troublesome dyskinesia'. The hope is that the steady release of drugs can improve both these metrics.

Exhibit 1: AP-CDLD Phase III trial design



Source: Intec

In November 2017, the company announced it was increasing the enrolment in the trial to 420 patients (after previously decreasing enrolment to 328 patients). One of the stated reasons for the increase was due to "higher than expected attrition rates" during the dosing lead-in periods. This is understandable considering that patients that were stabilized on their normal regimen had little incentive to undergo two six-week periods in which their dosing was not optimized. Additionally, the first 100 patients were required to undergo gastroscopy to evaluate the gastric retention properties of the AP-CDLD pill, which also resulted in patient withdrawals. The company stated on the YE17 results that this gastroscopy safety study has been completed, and that more than 300 patients have been enrolled on the trial. Enrolment is expected to be complete in H218 (previously Q318), and we expect results in 2019.

The company also announced in the 2017 results it would be doing an additional PK study on AP-CDLD comparing three times a day dosing to an equivalent dose of Sinemet (five times a day). The goal of this study is to directly demonstrate, based on blood levels of drug, that the AP formulation provides a more consistent exposure than Sinemet. Results are expected to be available in H218.

Cannabinoid program update

The company has been investigating an AP formulation of the cannabinoids cannabidiol (CBD) and tetrahydrocannabinol (THC) for pain-related disorders such as low back pain or fibromyalgia. The company previously completed a Phase I study of a co-formulation of the two drugs (AP-CBD/THC) in which it studied the PK profile compared to Sativex (GW Pharmaceuticals), a commercially available cannabis extract. It showed significant improvements in the PK of AP-CBD/THC compared to Sativex with an improvement of CBD exposure by 290% to 330% and THC exposure by 25% - 50%.

However, the company later stated it was investigating a redesign of the AP technology used for the combination to move forward, we assume because of the limited improvement in THC exposure. In the most recent update from the company, it appears that efforts to develop a combination product have been unsuccessful as the company has evaluated the program and decided instead to move forward with two separate formulations (AP-CBD and AP-THC). It stated that it intends to initiate two independent Phase I PK studies in H218.

Valuation

We have slightly decreased our valuation to NIS597m ($174m) or NIS22.91 ($6.68) per basic share from NIS619m ($176m) or NIS23.85 ($6.79) per basic share. This change is largely driven by lower net cash, offset by rolling forward our NPVs to the most recent period. We also expect to update our valuation with the release of data from the Phase III study of AP-CDLD in 2019.

Exhibit 2: Valuation of Intec Pharma

Development Program	Clinical stage	Prob. of success	Launch year	Launch pricing ($)	Peak sales ($m)	Patent/exclusivity protection	Royalty/ margin	rNPV (NISm)
AP-CDLD, US	Phase III	60%	2020	8,200	140	2029	47%	301
AP-CDLD, Europe	Phase III	60%	2020	4,900	107	2029	40%	192
AP-CDLD development costs	Phase III							-18
Unallocated costs (administrative costs, etc.)								-67
Total								408
Net cash and equivalents (30 September 2017) (NISm)								189
Total company value (NISm)								597
Total basic shares (m)								26.1
Value per basic share (NIS)								22.91
Options (m)								2.0
Total diluted shares (m)								28.1
Value per diluted share (NIS)								22.28

Source: Intec reports, Edison Investment Research

Financials

The company reported 2017 financials on 9 March 2018. The company had an operating loss of $29.2m for the year, driven primarily by R&D expenses associated with the Phase III clinical trial of AP-CDLD. Direct R&D expenses were $21.5m for the period, which was above our prior estimates

($19.4m). However, the company's stated enrolment to date (more than 300 patients), was below our estimates. As a result of these developments we have increased our expected R&D spend for 2018 to $18.3m (from $14.0m). In addition to direct R&D costs, the company also had to repay the Israeli Innovation Authority $2.8m, for a total R&D spend of $24.3m.

The company ended the year with $55.2 in net cash. In addition to operational spending, the company recorded $5.0m in capex (including advanced payments for PPE). We expect future capex growth to be limited given that the company has outsourced manufacturing for its AP technology. During the year the company received a net $63.1m from equity. Our future financing expectations remain unchanged, and we expect that cash-on-hand will be sufficient to bring the company to profitability in 2020.

Exhibit 3: Financial summary

$'000s	2016	2017	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	0	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	0	0	0
Research and development	(10,749)	(24,295)	(18,300)	(11,523)
Selling, general & administrative	(3,097)	(5,144)	(5,658)	(6,224)
EBITDA	(14,513)	(30,050)	(24,766)	(18,508)
Operating Profit (before amort. and except.)	(13,812)	(29,221)	(23,740)	(17,530)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(13,812)	(29,221)	(23,740)	(17,530)
Net Interest	450	157	157	157
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(13,362)	(29,064)	(23,583)	(17,373)
Profit Before Tax (IFRS)	(13,362)	(29,064)	(23,583)	(17,373)
Tax	0	(29)	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(13,362)	(29,093)	(23,583)	(17,373)
Profit After Tax (IFRS)	(13,362)	(29,093)	(23,583)	(17,373)
Average Number of Shares Outstanding (m)	11.4	17.7	27.4	28.7
EPS - normalised (c)	(116.72)	(164.74)	(86.15)	(60.43)
EPS - IFRS ($)	(1.17)	(1.65)	(0.86)	(0.60)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	4,047	8,206	7,825	7,518
Intangible Assets	0	0	0	0
Tangible Assets	4,047	8,206	7,825	7,518
Other	0	0	0	0
Current Assets	20,674	56,343	32,906	16,010
Stocks	0	0	0	0
Debtors	2,384	1,125	1,125	1,125
Cash	18,228	55,149	31,712	14,816
Other (restricted cash)	62	69	69	69
Current Liabilities	(1,152)	(1,854)	(1,935)	(1,433)
Creditors	(1,152)	(1,854)	(1,935)	(1,433)
Short term borrowings	0	0	0	0
Long Term Liabilities	(97)	0	0	0
Long term borrowings	0	0	0	0
Other long term liabilities	(97)	0	0	0
Net Assets	23,472	62,695	38,797	22,094
CASH FLOW				
Operating Cash Flow	(12,005)	(22,132)	(22,792)	(16,226)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(482)	(4,994)	(645)	(671)
Acquisitions/disposals	206	247	0	0
Financing	0	63,707	0	0
Dividends	0	0	0	0
Other	0	0	0	0
Net Cash Flow	(12,281)	36,828	(23,437)	(16,897)
Opening net debt/(cash)	(30,673)	(18,228)	(55,149)	(31,712)
HP finance leases initiated	0	0	0	0
Exchange rate movements	8	(120)	0	0
Other	(172)	213	0	0
Closing net debt/(cash)	(18,228)	(55,149)	(31,712)	(14,816)

Source: Intec reports, Edison Investment Research

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