EDISON

Intec Pharma

Clinical update

AP-CDB/THC performs in Phase I

Pharma & biotech

Intec Pharma announced on 3 August 2017 that it had completed the Phase I clinical trial of AP-CBD/THC in 21 healthy volunteers. AP-CBD/THC is a formulation of cannabidiol and tetrahydrocannabinol using Intec's proprietary accordion pill technology. The trial compared its safety, tolerability, and pharmacokinetics to the buccal cannabis extract, Sativex. AP-CBD/THC showed improved exposure, time at peak, and metabolism compared to Sativex without any safety or tolerability concerns.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/15	0.0	(7.2)	(0.92)	0.0	N/A	N/A
12/16	0.0	(13.4)	(1.17)	0.0	N/A	N/A
12/17e	0.0	(20.8)	(0.78)	0.0	N/A	N/A
12/18e	0.0	(17.3)	(0.62)	0.0	N/A	N/A

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

Exposure and time at peak increased over Sativex

Intec announced that AP-CBD/THC improved the exposure of CBD by 290% to 330% and THC by 25% to 50% compared to Sativex. This demonstrates that the AP formulation of these molecules can deliver these molecules to patients at pharmacologically relevant concentrations. Additionally, the time at peak concentration was 2-3x longer, suggesting that the gastroretentive properties of the AP formulation are effective at prolonging the dissolution of the drug.

No safety or tolerability issues raised

Intec reported that the clinical trial did not raise any safety or tolerability issues for AP-CBD/THC. No serious adverse effects were observed on the trial. These molecules have a well understood safety profile, although it is encouraging that this formulation can deliver a sufficient quantity of drug while maintaining tolerability.

Proposed indications: Back pain or fibromyalgia

The company stated that it will announce details regarding the future of the AP-CBD/THC program by YE17. It previously proposed two potential indications, neuropathic low back pain and fibromyalgia, both of which could potentially leverage the effect of cannabinoids in neuropathic pain. They are major indications with an estimated 5.5 million and 4 million adults, respectively, in the US.

Valuation: NIS737m ($205m), NIS28.39/share ($7.91)

We have increased our valuation to NIS737m ($205m) from NIS606m (~$166m), but reduced our per share valuation to NIS28.39 ($7.91) from NIS44.02 (~$12.04) per basic share largely as a result of the August 2017 offering of approximately $57.5m (12.2m shares at $4.70). The increase was partially offset by an increase in current and forecasted R&D spending because the company did not secure assistance from the Israel Innovation Authority (IIA). Following the offering, we do not believe the company will require any more cash to be able to reach profitability in 2020.

29 August 2017

Price	**NIS23.38**
Market cap	**NIS608m**

*Priced at 22 August 2017

NIS3.59/US$

Estimated net cash ($m) as at August 2017	71.5
Shares in issue	26.0m
Free float	83%
Code	NTEC
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance

%	1m	3m	12m
Abs	21.0	19.0	1.5
Rel (local)	23.9	21.5	3.2

52-week high/low	NIS23.4	NIS15.4

Business description

Intec Pharma is a drug delivery company that has developed the accordion pill, a novel gastroretentive controlled release formulation. The company is currently using this technology to develop AP-CDLD for Parkinson's in Phase III, AP-ZP for insomnia completed Phase II, and AP-CBD/THC completed Phase I for pain indications.

Next events

AP-CDLD enrolment complete	Q417
AP-CBD/THC indication announced	YE17

Analysts

Maxim Jacobs	+1 646 653 7027
Nathaniel Calloway	+1 646 653 7036

healthcare@edisongroup.com

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AP-CBD/THC outperforms Sativex in Phase I

Intec announced on 3 August 2017 that it had completed the Phase I study of the cannabidiol/tetrahydrocannabinol accordion pill (AP-CBD/THC). The goal of the study was to investigate the safety and pharmacokinetics of two AP-CBD-THC formulations compared to Sativex (GW Pharmaceuticals), a cannabis extract formulated for buccal delivery that contains both CBD and THC. It had a three-way crossover design and enrolled 21 healthy volunteers.

Intec reported that AP-CBD/THC had significant improvements in the pharmacokinetics compared to Sativex. Exposure of CBD was improved by 290% to 330% and exposure of THC was improved by 25% to 50% over Sativex. It is difficult to speculate as to the reason for the increased exposure as there are multiple factors involved including different route of administration and different doses, but these data demonstrate the AP-CBD/THC had more than sufficient exposure of these molecules to reach pharmacologically relevant concentrations. According to the Sativex prescribing information, the drug had an area under the curve (AUC) for THC (at 21.6mg administered) of 1,362 ng/mL/min, compared to 5,987.9 ng/mL/min for vaporized THC extract (8mg).

Although Sativex is formally a buccal formulation, there is significant evidence to suggest that a large portion of it is being administered orally in practice. There is a pronounced food effect, and when taken at the same time as food the AUC for THC can increase 1.6 to 2.8 fold and CBD can increase 3.3 to 5.1 fold. This highlights some of the issues that have been encountered with orally administered cannabinoids. Although AP-CBD/THC is an oral formulation, the specific gastroretentive properties of the AP should improve the consistency of its absorption. These specific details have not been released yet, however, the company did announce that AP-CDB/THC showed a 2-3x improvement in the “time of peak concentration” over Sativex according to the release, which indicates that gastroretention is effectively extending the dissolution of drugs and can potentially improve the oral profile of these molecules.

A particularly interesting finding from the study was that the AP-CBD/THC formulation showed a reduction in formation of THC metabolites of 25% or greater, which suggests that the rate of THC metabolism is reduced compared to Sativex. This is interesting considering that any THC delivered buccally will avoid first pass metabolism in the liver, whereas AP-CBD/THC is purely oral and cannot avoid hepatic exposure. This suggests some degree of non-linearity in the metabolism of THC, although the precise mechanism is unknown at this time.

Finally, the company announced that the drug was safe and well tolerated, with no serious adverse effects. This is not particularly surprising given the well understood safety profile of these molecules, but is reassuring nonetheless. The company stated that it would provide an update on its plans regarding the program by the end of 2017. It previously announced its intent to study AP-CBD/THC for the treatment of pain indications including low back pain or fibromyalgia. These are both exceptionally large markets with a high degree of unmet medical need. Approximately 10% of US adults report chronic lower back pain,[1] 17% of which is primarily neuropathic in origin,[2] corresponding to a target market of approximately 5.5 million people. Fibromyalgia, by comparison, is estimated to affect four million adults in the US according to the CDC.

[1] Freburger JK, et al. (2009) The Rising Prevalence of Chronic Low Back Pain. *J. Am. Med. Assoc. Int. Med.* 169, 251-258.

[2] Torrance N, et al. (2006) The Epidemiology of Chronic Pain of Predominantly Neuropathic Origin. Results From a General Population Survey. *J. Pain* 7, 281-289.

Valuation

We have increased our valuation to NIS737m ($205m) from NIS606m (~$166m). This change is largely driven by the recent offering of approximately $57.5m ($53.6m net), although this has reduced our per share valuation to NIS28.39 ($7.91) from NIS44.02 (~$12.04) per basic share. The valuation is negatively affected by changes to the expected R&D spending. We previously accounted for cash from the Israel Innovation Authority (IIA) to offset a portion of R&D spending ($4.5m in 2016), but the company did not report any grants for H117. These factors had a negative impact on cash for the period and R&D spending projections for future periods. Additionally, we have delayed the launch of AP-ZP to 2021 due to the current lack of a partner. These effects were offset by rolling forward our NPVs to H117. We do not include the AP-CBD/THC programme in our valuation as the target indication has not been announced. However, we find the Phase I clinical results to be encouraging and expect to add this program to our valuation shortly. We also expect to update our valuation with the release of data from the Phase III study of AP-CDLD in 2018.

Exhibit 1: 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%	2019	7,700	111	2029	47%	293
AP-CDLD, Europe	Phase III	60%	2019	4,600	85	2029	40%	187
AP-CDLD development costs	Phase III							-22
AP-ZP (US and Europe)	Phase III ready	40%	2021	700	154	2028	15%	51
AP-ZP Licensing upfront	Phase III ready	30-50%	2018					34
Unallocated costs (administrative costs, etc.)								-63
Total								480
Net cash and equivalents (H117 + offering) (NISm)								257
Total firm value (NISm)								737
Total basic shares (m)								26.0
Value per basic share (NIS)								28.39
Options (m)								0.1
Total diluted shares (m)								26.1
Value per diluted share (NIS)								28.24

Source: Intec reports, Edison Investment Research

Financials

Intec reported a loss of $11.2m for H117. This is increased compared to H116 ($6.4m) predominantly due to an increase in R&D expenses. The company did not receive any cash from IIA for the quarter to offset R&D, which it stated was due to the requirement that product be manufactured in Israel. The company may receive assistance from IIA in the future if this requirement is met. Combined with this, there was higher than expected spending on the AP-CDLD clinical trial, although this reflects faster than expected enrolment. These two factors have increased our expected R&D spending for 2017 to $17.1m from $9.9m. The company ended the period with $17.9m in cash following the $10m (gross) private placement in March 2017. This was subsequently further supplemented by the August 2017 public offering of approximately $57.5m (12.2m shares at $4.70, $53.6m net). We believe that this is sufficient capital for the company to reach profitability in 2020. Our previous financing requirement was $10m, so Intec now has a significant funding cushion.

Exhibit 2: Financial summary

$'000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	0	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	0	0	0
Research and development	(4,815)	(10,749)	(17,098)	(13,208)
Selling, general & administrative	(2,788)	(3,097)	(4,172)	(4,589)
EBITDA	(8,330)	(14,513)	(21,742)	(18,269)
Operating Profit (before amort. and except.)	(7,584)	(13,812)	(21,236)	(17,763)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(7,584)	(13,812)	(21,236)	(17,763)
Net Interest	404	450	450	450
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(7,180)	(13,362)	(20,786)	(17,313)
Profit Before Tax (IFRS)	(7,180)	(13,362)	(20,786)	(17,313)
Tax	0	0	0	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(7,180)	(13,362)	(20,786)	(17,313)
Profit After Tax (IFRS)	(7,180)	(13,362)	(20,786)	(17,313)
Average Number of Shares Outstanding (m)	7.8	11.4	26.5	27.8
EPS - normalised (c)	(92.16)	(116.72)	(78.49)	(62.26)
EPS - IFRS ($)	(0.92)	(1.17)	(0.78)	(0.62)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	4,076	4,047	4,042	4,058
Intangible Assets	0	0	0	0
Tangible Assets	4,076	4,047	4,042	4,058
Other	0	0	0	0
Current Assets	33,096	20,674	65,444	48,063
Stocks	0	0	0	0
Debtors	2,361	2,384	1,326	1,326
Cash	30,673	18,228	64,056	46,675
Other	62	62	62	62
Current Liabilities	(614)	(1,152)	(1,718)	(1,437)
Creditors	(614)	(1,152)	(1,718)	(1,437)
Short term borrowings	0	0	0	0
Long Term Liabilities	(327)	(97)	(97)	(97)
Long term borrowings	0	0	0	0
Other long term liabilities	(327)	(97)	(97)	(97)
Net Assets	36,231	23,472	67,671	50,588
CASH FLOW				
Operating Cash Flow	(7,931)	(12,005)	(16,796)	(16,859)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(1,384)	(482)	(501)	(521)
Acquisitions/disposals	0	206	0	0
Financing	32,452	0	63,125	0
Dividends	0	0	0	0
Other	13	0	0	0
Net Cash Flow	23,150	(12,281)	45,828	(17,380)
Opening net debt/(cash)	(7,742)	(30,673)	(18,228)	(64,056)
HP finance leases initiated	0	0	0	0
Exchange rate movements	(232)	8	0	0
Other	13	(172)	0	0
Closing net debt/(cash)	(30,673)	(18,228)	(64,056)	(46,675)

Source: Intec reports, Edison Investment Research

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
295 Madison Avenue, 18th Floor
10017, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205
95 Pitt Street, Sydney
NSW 2000, Australia

Tel Aviv +44 (0)20 3734 1007
Medinat Hayehudim 60
Herzilya Pituach, 46766
Israel