EDISON

Intec Pharma

Company update

Getting closer to data

Pharma & biotech

Intec is moving closer to data from its clinical programmes to validate the utility of its unique drug delivery platform, the accordion pill (AP). The AP is specifically designed to improve gastroretention as a controlled release solution for difficult-to-formulate drugs. The lead programme is a Phase III study of AP-CDLD (carbidopa and levodopa) in Parkinson's, which is expected to be completely enrolled in Q417. It is also in a Phase I clinical study (targeting Q317 completion) of AP-CDB/THC (cannabidiol and tetrahydrocannabinol) for the treatment of pain and is seeking a development partner for is sleep aid, AP-ZP (zaleplon).

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	(12.8)	(0.89)	0.0	N/A	N/A
12/18e	0.0	(13.6)	(0.89)	0.0	N/A	N/A

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

AP-CDLD to smooth Parkinson's peaks and valleys

A persistent problem affecting Parkinson's patients is that the primary drug used to treat the disease, levodopa has an exceptionally poor pharmacokinetic profile, leading to peaks in drug concentration when patients are troubled by dyskinesia and valleys when disease symptoms are not controlled. AP-CDLD directly addresses these shortcomings through improved gastroretention, providing a smooth profile and more consistent drug delivery.

Phase III fully enrolled by end of 2017

In response to feedback from key opinion leaders, the company reduced the size and number of trial sites for the Phase III trial of AP-CDLD from 460 to 328 patients. This will enable the trial to be fully enrolled by Q417. Patients are followed for 27 weeks, and we therefore expect data from the trial in H218.

Testing the AP solution to cannabinoids

Cannabinoids are generally very greasy, insoluble drugs and as a result, have somewhat unpredictable and variable pharmacokinetics. This can potentially limit the application of these drugs for novel indications, especially those, such as pain, that require precise dosing to provide consistent relief. The company in in a Phase I study to determine if an AP formulation of CBD and THC can provide consistency, and it intends to use the data to design a future Phase II study investigating it for neuropathic low back pain or fibromyalgia.

Valuation: NIS606m or NIS44.02 per share

We are leaving our valuation unchanged at NIS606m (~$166m) and NIS44.02 (~$12.04) per basic share. We expect to add AP-CBD/THC to our valuation following the Phase I results and more clarity about its path to market. We expect the company to need $10m in financing before approval of AP-CDLD in 2019.

27 July 2017

Price*	**NIS19.93**
Market cap	**NIS275m**

*Priced at 26 July 2017

NIS3.65/US$

Estimated net cash ($m) at March 2017	27.2
Shares in issue	13.8m
Free float	83%
Code	NTEC
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance

%	1m	3m	12m
Abs	4.8	(0.3)	17.9
Rel (local)	4.1	(3.2)	15.4

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 in Phase I for pain indications.

Next events

AP-ZP partnering discussions	Ongoing
AP-CBD/THC Phase I completion	Q317
AP-CDLD enrolment complete	Q417

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Edison profile page

A pipeline in a pill

Intec Pharma is a specialty pharmaceutical company developing novel formulations of approved medications using its proprietary "accordion pill" (AP) technology. The AP is designed to expand within the stomach to a larger flat sheet to improve gastric retention times and can be formulated with a combination of immediate and controlled release properties. The company currently has five development programmes (Exhibit 1). The lead programme is an AP formulation of the Parkinson's drugs carbidopa and levodopa (AP-CDLD) in an ongoing Phase III study. The trial is expected to complete enrolment in Q417. The second most advanced programme is an AP formulation of the sleep aid zaleplon (AP-ZP), which is Phase III ready pending a partnership. The company recently initiated a Phase I clinical trial investigating the safety, tolerability, and pharmacokinetics of the cannabinoids cannabidiol (CBD) and tetrahydrocannabinol (THC) in an AP format (AP-CBD/THC). The Phase I trial is expected to be complete in Q317 and the data from this study will be used to design future studies investigating the drug for the treatment of pain indications such as neuropathic low back pain and fibromyalgia. The company has also completed a Phase I study of an undisclosed drug for the prevention of ulcers associated with nonsteroidal anti-inflammatories (NSAIDs), as well as a preclinical collaboration with Biogen, although we have few details.

Exhibit 1: Intec pipeline

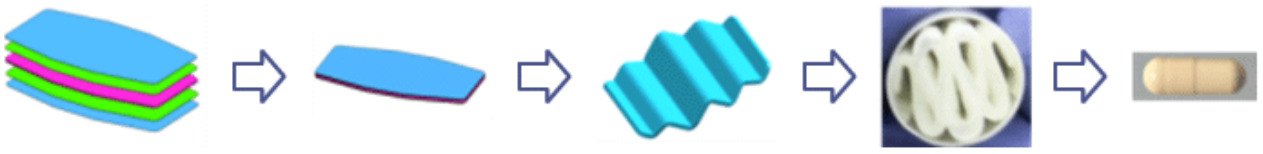
Programme	Stage	Indication	Molecule(s)
AP-CDLD	Phase III	Parkinson's	Carbidopa and levodopa
AP-ZP	Phase III ready	Insomnia	Zaleplon
Undisclosed drug	Phase I	Prevention of NSAID induced gastroduodenal and small bowel ulcers	Undisclosed
Biogen partnership	Preclinical	Undisclosed	Approved Biogen drug
AP-CBD/THC	Phase I	Neuropathic low back pain and fibromyalgia	Cannabinoids

Source: Intec Pharma

Engineering a new type drug delivery

Intec's key innovation is the development of the accordion pill drug delivery platform. The AP technology uses a typical gel-cap pill, which dissolves in the stomach to release a folded two-dimensional composite film impregnated with the drug of interest. The AP expands upon exposure to the gastric medium to 3.5cm in length, and is retained in the stomach while the drug is released.

Exhibit 2: Composition and assembly of accordion pill



Source: Intec Pharma

The AP platform is versatile and can be adapted to an array of drugs and release profiles. Each accordion pill is comprised of a series of layers, which can be formulated independently to control the drug release profile:

- Inner drug matrix – a polymer matrix impregnated with the drug of interest. The matrix is designed to dissolve when exposed to the gastric medium.
- Outer membranes – an "envelope" that surrounds the inner matrix. These membranes are hydrophilic and swell upon exposure to the gastric medium, but are resistant to degradation in the stomach. The swelling of these membranes exposes the inner drug layer to the gastric

juices allowing it to dissolve, while retaining the physical profile of the AP. This layer fully dissolves in the lower digestive tract.

- Optional immediate release layer – this is a layer of drug in a matrix or film applied to the outside of the AP, designed to dissolve immediately after the drug reaches the stomach.

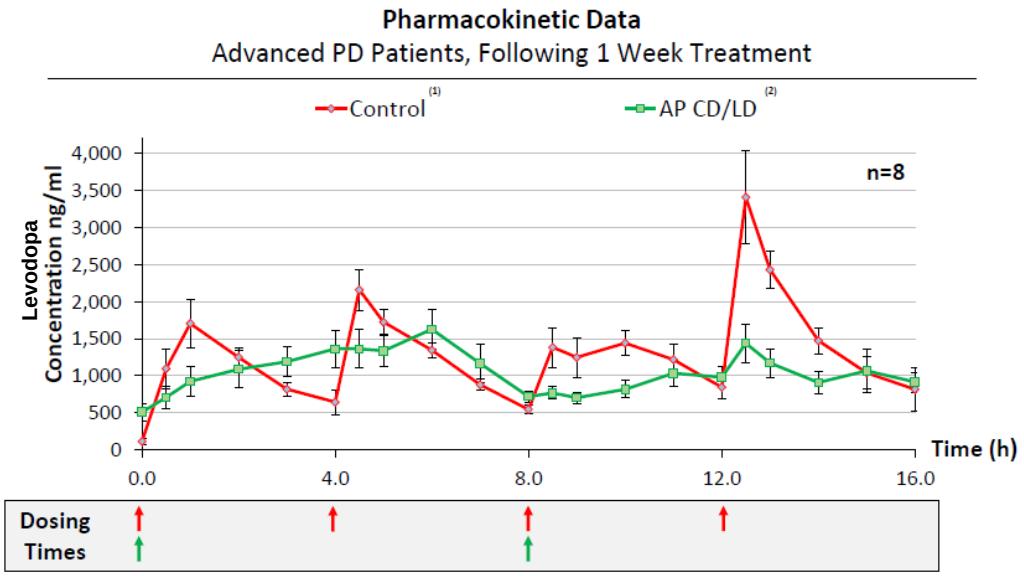
Intec is currently investigating the formulation for a series of controlled release (CR) applications because of a set of distinct advantages the AP has over other existing CR formulations. One of the central characteristics of the AP is that its expansion in the stomach leads to unprecedented gastric retention times (eight to 12 hours), as measured through MRI imaging. The gastric retention is driven by three factors that discourage passage through the pylorus: the device's physical size, its two-dimensional profile, and its rigidity. Unlike other CR formulations that release drugs continuously as they pass through the digestive tract, the AP isolates this dissolution to the stomach, and the drug is absorbed primarily in the duodenum and proximal small intestine, which can be important for drugs that have local activity or specific absorption in these regions. This provides a uniform absorption profile and can potentially improve plasma levels by prolonging the absorption phase. Moreover, the solubilisation of the drug is aided by the high concentration of bile acids. This consideration is important as an increasing number of new drugs are of low solubility; up to 60% by some measures.[1]

AP-CDLD

The company's lead programme, AP-CDLD leverages both of these advantages of gastroretention to improve the delivery of a drug and the patient experience. Parkinson's patients on carbidopa and levodopa typically cycle between periods in which disease symptoms dominate (so-called off periods) and periods in which these symptoms are well controlled (on periods). Patients can go through several of these cycles per day, because the pharmacokinetics of levodopa lead to both fast spiking of the drug in the bloodstream and fast clearance. Moreover, some patients on high concentrations of a drug experience significant adverse effects such as dyskinesia during the periods when the drug spikes. Extended release formulations of the drug tend to perform poorly because levodopa is preferentially absorbed in the proximal small intestine, and it is poorly soluble in the gut. AP-CDLD therefore has the potential to significantly improve the pharmacokinetic profile of the drug by providing a smooth dissolution profile and delivering the active molecules directly to the proximal small intestine where they are absorbed. This was demonstrated during the Phase II clinical trial of the drug, in which it was shown that patients receiving AP-CDLD had fewer peaks and valleys than immediate release carbidopa and levodopa (Exhibit 3), and that this translated into an improvement in off time comparable to Rytary (controlled release carbidopa/levodopa) and Comtan (catechol-O-methyltransferase COMT inhibitor) (Exhibit 4). The ongoing Phase III clinical trial will enrol 328 patients and will compare the reduction in off time (primary endpoint) and reduction in dyskinesia (secondary endpoint) with Sinemet (immediate release carbidopa/levodopa).

[1] Ku, MS (2008) Use of the Biopharmaceutical Classification System in Early Drug Development. *AAPS J.* 10, 208-212.

Exhibit 3: Levodopa blood levels with AP-CDLD and IR carbidopa/levodopa



Source: Intec Pharma. Note: (1) 18.7mg carbidopa, 187.5 mg levodopa per dose; (2) 50mg carbidopa, 375mg levodopa per dose.

Exhibit 4 AP-CDLD Phase II efficacy results

	AP-CDLD 50/375mg (n=16)			AP-CDLD 50/500mg (n=18)			Rytary (n=393)			Comtan (n=205)		
	Current treatment	AP-CDLD	p	Current treatment	AP-CDLD	p	CDLD	Rytary	p	Placebo +CDLD	Comtan + CDLD	p
Off time (h)	4.3	2.4	<0.0001	5.1	2.8	<0.0001	4.88	3.87	<0.0001	5.3	4.2	<0.001
On time with troublesome dyskinesia (h)	0.7	0.6	n.s.	1.2	0.7	0.002	0.45	0.52	n.s.	increasedError! Bookmark not defined.		0.002
Number of daily LD administrations	6.3	3.5	<0.0001	5.3	4	<0.0001	5.1	3.6	<0.0001	6.2	5.8	<0.001

Source: Intec Pharma, Rytary approval review documents, Comtan approval review documents, Parkinson's Study Group. Note: Rytary and Comtan data reflect patients stabilised on different dosing regimens. CD=carbidopa, LD=levodopa, n.s.=not significant.

AP-CBD/THC

Intec announced in March 2017 that it has initiated a Phase I clinical trial of an AP formulation CBD and THC. There are several aspects of cannabinoid pharmacology that could potentially be improved by the AP formulation. Cannabinoids have a low oral bioavailability measured at an average of 6% for THC[2] and CBD,[3] although with high levels of variability between individuals and doses even when administered under similar conditions. THC and CBD are very oily molecules that dissolve poorly in the aqueous gastric medium. The dissolution and absorption of the drug is aided in the gut by bile acids. The AP device is specifically designed to maximise the exposure of drugs to bile acids secreted in the upper gastrointestinal tract, and an AP-CBD/THC formulation may significantly improve the drug's oral profile. The goal of the Phase I study is to examine this profile and determine the applicability of the formulation to any future indications.

The two indications being pursued by the company were neuropathic low back pain and fibromyalgia, although they have made no commitments to study either. Although both of these indications can be described as pain disorders, their aetiologies are significantly different. Low back pain can be mechanical in nature due to stress on the muscles or bones of the lower back, or

[2] Ohlsson A, et al (1980) Plasma delta-9 tetrahydrocannabinol concentrations and clinical effects after oral and intravenous administration and smoking. *Clin. Pharmacol. Ther.* 28, 409-16.

[3] Agurell S, et al. (1981). Interaction of THC with cannabinol and cannabidiol following oral administration in man. Assay of cannabinol and cannabidiol by mass fragmentography. Experientia 37, 1090–2.

neuropathic as in the case of sciatica, and the company has stated that it intends to focus on the neuropathic variety. Fibromyalgia is a poorly understood disorder characterised by chronic diffuse pain in multiple regions of the body. Although the cause of the disorder is not well understood, it has a high comorbidity with mood disorders and appears to be caused by a defect of the nervous system. The Phase I clinical study is expected to be complete in Q317.

AP-ZP

Intec is developing AP-ZP as a new sleep aid with the goal of providing consistent sleep without any next-day after effects. Zaleplon is an insomnia treatment that was previously marketed under the name of Sonata, and is part Z-drug class. Zaleplon has a half-life of approximately one hour (compared to 2.6 hours for Ambien and six hours for Lunesta).[4] Because of this, the drug can be taken before even relatively short periods of rest (less than two hours) without leading to any residual "hangover" effects.[5] The hangover experienced by patients taking prescription hypnotics is an issue of significant public health interest, and the FDA has ordered a reduction in the dosing recommendations for both Ambien and Lunesta on the basis of post-marketing reports of impaired function the day after taking the medications. However, when compared to Ambien, patients taking zaleplon saw less improvement in overall sleep quality,[6] which might be tied to the short half-life. The company believes that it can achieve a best of both worlds solution by providing the controlled release of zaleplon with an AP throughout the night to maintain sleep quality and still avoid morning hangover effects. Moreover, the AP is the ideal platform because poor solubility limits the bioavailability of the drug in traditional formulations.[7]

AP-ZP's most recent and most comprehensive clinical trial was a Phase II study that assessed its efficacy in a set of sleep parameters and measured the residual next-day effects in 83 individuals. The trial was of a crossover design, with patients receiving either placebo or active drug over six nights. The trial demonstrated a statistically significant improvement in both total sleep time and the latency to persistent sleep (Exhibit 5). This improvement in both metrics was more pronounced than what was seen in previous studies of Sonata (10mg),[8] but less than that seen with Ambien[9] (Exhibit 5). However, we should note that these results from different trials are not strictly comparable, and were made with patients with different baseline conditions.

Exhibit 5: Assessment of sleep parameters

	AP-ZP 10/15mg (n=83)				Ambien 10mg (n=125)				Sonata 10mg (n=67)			
(minutes)	Placebo	AP-ZP	Diff.	p	Placebo	Ambien	Diff.	p	Placebo	Sonata	Diff.	p
Total sleep time	364.11	382.39	18.28	<0.001	382.73	418.23	35.5	0.0001	400	402	2	n.s.
Wake time after sleep onset	75.57	70.44	-5.13	0.27	78.12	58.17	-19.95	0.033				
Latency to persistent sleep	45.46	31.6	-13.86	<0.001	30.76	12.65	-18.11	0.004	25.38	19.25	-6.13	0.039

Source: Intec, Randal et al., Walsh et al. Note: AP-ZP data at six nights, Ambien data at one month, Sonata data at four to six nights.

AP-ZP may provide advantages over Ambien in terms of residual next-day effects (Exhibit 6). In the AP-ZP clinical trial, the drug did not show any significant worsening in the digit symbol substitution test (a measurement of cognition) or on a memory test, compared to placebo. There was a

4 Respective prescribing information.

5 Weitzel KW, et al. (2000) Zaleplon: a pyrazolopyrimidine sedative-hypnotic agent for the treatment of insomnia. *Clin. Therapeutics* 22(11), 1254-1267.

6 Boland YD, et al. (2004) Newer hypnotic drugs for the short-term management of insomnia: a systematic review and economic evaluation. *Health Tech. Ass.* 8(24).

7 Rosen AS, et al. (1999) Zaleplon pharmacokinetics and absolute bioavailability. *Biopharm. Drug Dispo.* 20(3), 171-175.

8 Walsh JK, et al (1998) Efficacy and Tolerability of 14-Day Administration of Zaleplon 5mg and 10mg for the Treatment of Primary Insomnia. *Clin. Drug Invest.* 16(5), 347-354.

9 Randal S et al. (2012) Efficacy of Eight Months of Nightly Zolpidem: A Prospective Placebo-Controlled Study. *Sleep* 35, 1551-1557.

statistically significant increase in the patient assessment of symptoms on a visual analogue scale, but the magnitude of the increase was small (3%). By comparison, the hangover effect of Ambien can be significant. The FDA issued a warning letter in 2013 stating that up to 15% of women and 3% of men had blood levels significant enough to cause impairment the morning after taking immediate release Ambien. For Ambien CR, the rates were even higher, with 33% of women and 25% of men. The company has stated that it intends to seek a partner to commercialise AP-ZP prior to proceeding with a Phase III clinical trial.

Exhibit 6: Residual effects of AP-ZP

	Placebo	AP-ZP	Difference	p
Digit symbol substitution test	41.7	41.6	-0.1	0.87
Memory test	5.55	5.51	-0.04	0.81
Visual analogue scale	55.34	58.63	3.29	0.021

Source: Intec Pharma

Valuation

We are leaving our valuation unchanged at NIS606m (~$166m) and NIS44.02 (~$12.04) per basic share. We currently do not include the AP-CBD/THC programme in our valuation because the company has not announced a precise target indication for the programme, although we expect to add this to our valuation with more details following the completion of the Phase I trial expected in Q317. We also expect to update our valuation in the event of partnering discussions for AP-ZP and the release of data from the Phase III study of AP-CDLD in 2018.

Exhibit 7: Valuation of Intec Pharma

Development programme	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%	281
AP-CDLD, Europe	Phase III	60%	2019	4,600	85	2029	40%	180
AP-CDLD development costs	Phase III							-23
AP-ZP (US and Europe)	Phase III ready	40%	2020	700	155	2028	15%	60
AP-ZP Licensing upfront	Phase III ready	30-50%	2018					33
Unallocated costs (administrative costs, etc.)								-24
Total								507
Net cash and equivalents (YE16 + offering) ($m)								100
Total firm value (NISm)								606
Total basic shares (m)								13.8
Value per basic share (NIS)								44.02
Options (m)								0.1
Total diluted shares (m)								13.9
Value per diluted share (NIS)								43.58

Source: Intec reports, Edison Investment Research

Financials

We have not updated our financial forecasts at this time. The company ended 2016 with $18.2m in cash and equivalents, which has subsequently been supplemented with a $10m (gross) private placement (2.3m shares at $4.40). We expect that the company will need $10m in additional financing to bring it through approval of AP-CDLD and profitability in 2019. We include this as illustrative debt in 2018.

Exhibit 8: Financial summary

$'000s	2014	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	0	0	0	0	0
Cost of Sales	0	0	0	0	0
Gross Profit	0	0	0	0	0
Research and development	(3,409)	(4,815)	(10,749)	(9,916)	(10,332)
Selling, general & administrative	(2,609)	(2,788)	(3,097)	(3,407)	(3,747)
EBITDA	(6,369)	(8,330)	(14,513)	(13,795)	(14,551)
Operating Profit (before GW and except.)	(5,784)	(7,584)	(13,812)	(13,289)	(14,045)
Intangible Amortisation	0	0	0	0	0
Exceptionals/Other	0	0	0	0	0
Operating Profit	(5,784)	(7,584)	(13,812)	(13,289)	(14,045)
Net Interest	91	404	450	450	450
Other (change in fair value of warrants)	0	0	0	0	0
Profit Before Tax (norm)	(5,693)	(7,180)	(13,362)	(12,839)	(13,595)
Profit Before Tax (IFRS)	(5,693)	(7,180)	(13,362)	(12,839)	(13,595)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(5,693)	(7,180)	(13,362)	(12,839)	(13,595)
Profit After Tax (IFRS)	(5,693)	(7,180)	(13,362)	(12,839)	(13,595)
Average Number of Shares Outstanding (m)	4.8	7.8	11.4	14.5	15.2
EPS - normalised ($)	(1.18)	(0.92)	(1.17)	(0.89)	(0.89)
EPS - IFRS ($)	(1.18)	(0.92)	(1.17)	(0.89)	(0.89)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	4,397	4,076	4,047	4,042	4,058
Intangible Assets	0	0	0	0	0
Tangible Assets	4,397	4,076	4,047	4,042	4,058
Other	0	0	0	0	0
Current Assets	8,105	33,096	20,674	18,849	15,941
Stocks	0	0	0	0	0
Debtors	288	2,361	2,384	2,384	2,384
Cash	7,742	30,673	18,228	16,403	13,495
Other	75	62	62	62	62
Current Liabilities	(184)	(614)	(1,152)	(1,076)	(1,137)
Creditors	(184)	(614)	(1,152)	(1,076)	(1,137)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(1,164)	(327)	(97)	(97)	(10,097)
Long term borrowings	0	0	0	0	(10,000)
Other long term liabilities	(1,164)	(327)	(97)	(97)	(97)
Net Assets	11,154	36,231	23,472	21,718	8,765
CASH FLOW					
Operating Cash Flow	(4,751)	(7,931)	(12,005)	(11,324)	(12,386)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(76)	(1,384)	(482)	(501)	(521)
Acquisitions/disposals	2,865	0	206	0	0
Financing	4,682	32,452	0	10,000	0
Dividends	0	0	0	0	0
Other	(9)	13	0	0	0
Net Cash Flow	2,711	23,150	(12,281)	(1,825)	(12,908)
Opening net debt/(cash)	(5,400)	(7,742)	(30,673)	(18,228)	(16,403)
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	(369)	(232)	8	0	0
Other	0	13	(172)	(0)	0
Closing net debt/(cash)	(7,742)	(30,673)	(18,228)	(16,403)	(3,495)

Source: Intec reports, Edison Investment Research

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