EDISON

Therapix Biosciences

Earnings update

THX-ULD01 to focus on TBI

Pharma & biotech

Therapix reported H117 results and provided a company update in which it announced that the planned development program for sublingual ultra-low dose THC (THX-ULD01) will focus on the treatment of traumatic brain injury (TBI). The program is planned to enter a Phase I pharmacokinetic study in Q417, expected to take one month to complete. The company also reported that the Phase IIa Tourette's study of THX-TS01 was going smoothly and eight (of 18) patients have completed the trial, seven of whom opted to remain on the drug.

Year end	Revenue ($m)	PBT* ($m)	EPADS* ($)	DPADS ($)	P/E (x)	Yield (%)
12/16	0.0	(1.7)	(1.80)	0.0	N/A	N/A
12/17e	0.0	(3.6)	(0.97)	0.0	N/A	N/A
12/18e	0.0	(7.0)	(1.81)	0.0	N/A	N/A
12/19e	0.0	(11.5)	(2.85)	0.0	N/A	N/A

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

TBI is a major unmet medical need

TBI is one of the most common medical conditions affecting western countries. In the US there are approximately 2.5m emergency room visits per year from TBI, 300,000 of which result in a hospital in-stay. There is significant need for agents to improve cognitive impairment following TBI, as approximately 37% of patients admitted to the hospital have long-term cognitive disability following the event.

Patients electing to stay on THX-TS01

Therapix announced that the ongoing Phase IIa trial at Yale examining THX-TS01 for Tourette's is on schedule to complete enrolment in September or October 2017 and be complete around YE17. Twelve patients have been enrolled in the study and the company has data on eight patients who have completed the study, of whom seven have elected to remain on drug for an additional three months, suggesting that the formulation is tolerable and has a perceived benefit.

Phase IIb study moving to the US

The company previously announced that it would be participating in an investigator-sponsored Phase IIb study comparing THX-TS01 to placebo at Hannover Medical School. It announced on the H117 earnings call that this study would be moved to a site in the US instead. This has resulted in a small delay in the trial initiation (From Q317 to Q417), and the trial is expected to be complete in H218.

Valuation: Increased to $41.9m or $11.98 per ADS

We have increased our valuation to $41.9m or $11.98 per ADS, from $38.4m or $10.97 per ADS. This change was largely driven by the addition of THX-ULD01 to our model, because the company announced TBI as the target indication. We arrive at a risk-adjusted NPV of $5.4m based on a 5% probability of success. We expect the program to launch in 2022. We have increased our financing requirement to $27m from $25m based on higher than expected SG&A ($1.4m) for H117.

18 August 2017

Price	**US$5.31**
Market cap	**US$19m**
	NIS3.62/US$
Net cash ($m) at 30 June 2017	11.8
ADSs in issue	3.5m
Free float	92.5%
Code	TRPX
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance

%	1m	3m	12m
Abs	(19.6)	(18.3)	(33.8)
Rel (local)	(18.7)	(20.7)	(40.5)

52-week high/low	US$10.1	US$5.3

Business description

Therapix Biosciences is an Israeli pharmaceutical company developing two cannabinoids to treat Tourette syndrome and mild cognitive impairment. It is currently in Phase IIa and soon to begin Phase I, respectively, and owns or licenses several IPs for cannabinoid nasal and sublingual administration.

Next events

THX-ULD01 Phase I	Q417
THX-TS01 Phase IIa complete	YE17

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Edison profile page

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THX-ULD01 focus on traumatic brain injury

Therapix announced with its Q217 financial report that the company would focus its efforts developing THX-ULD01, a sublingual ultra-low dose formulation of THC, for traumatic brain injury (TBI). The company had previously discussed developing the drug for patients with mild cognitive impairment (MCI) associated with Alzheimer's, but this indication now appears to be deprioritized. Historically, Alzheimer's has been a difficult area of drug development with many prominent failures, and TBI may provide a quicker pathway to market. The company has stated that it is currently determining the optimal regulatory pathway for the program, and that these considerations have delayed the planned Phase I pharmacokinetic study of the drug. The pharmacokinetic study is currently planned to initiate in Q417 and take approximately one month. Following the Phase I, the company will be initiating a proof-of-concept study enrolling patients in the acute phase of the TBI, which is typically patients as they are admitted to the emergency room.

TBI is common in the US and in Europe. The Centers for Disease Control and Prevention estimates that 824 out of every 100,000 will have a TBI related emergency room visit, and 92 per 100,000 will have a hospital stay.[1] The rate of hospital discharges for TBI is lower in Europe (and highly variable by country) at 287 per 100,000, but the majority of these (81%) involve hospital stays.[2] The need for a solution to address cognitive impairment following a TBI is significant. Of patients admitted to a hospital, 37% have long lasting disability following the event.[3]

THX-TS01 program update

Therapix announced that 12 patients have been enrolled on in its 18-person Phase IIa study being performed at Yale, with the 13th patient scheduled to be enrolled around the time of the call. The company predicted at this pace that the last patient would be enrolled in late September or early October. Patients are treated for 12 weeks on the trial, and this enrolment schedule is on time to complete around YE17. The company has data on eight patients who have completed the trial, of whom seven have elected to remain on the treatment for an additional three months. This level of interest among patients is encouraging because it suggests some degree of perceived benefit and that the treatment is tolerable. There have not been any reported safety issues to date, which is consistent with the known profile of cannabinoids.

The company also provided an update on the planned placebo-controlled Phase IIb trial. This trial was originally planned as an investigator-sponsored trial to be conducted at Hannover Medical School, but the company announced that it now plans to perform the study in the US. Bringing on a US site for the study will cause a delay in its initiation from Q317 to Q417. The trial will observe patients over 13 weeks and based on this new schedule the trial should be complete in H218.

Valuation

We have increased our valuation to $41.9m or $11.98 per ADS, from $38.4m or $10.97 per ADS. We have added the TBI program to our valuation and determined a risk-adjusted NPV of $5.4m for

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1 Centers for Disease Control and Prevention. Get the Stats on Traumatic Brain Injury in the United States. www.cdc.gov/TraumaticBrainInjury accessed on 10 August 2017.

2 Majdan M, et al. (2016) Epidemiology of traumatic brain injuries in Europe: a cross-sectional analysis. *Lancet Pub. Health* 1, e76-83.

3 Thurman DJ, et al. (1999) Traumatic Brain Injury in the United States: A Public Health Perspective. *Head Traum. Rehab.* 14, 602-615.

the program. This is based on a 5% probability of success, which reflects the lack of in-human data regarding the use of ultra-low dose THC for this indication. We assume the target market will be the approximately 300,000 patients in the US who have severe enough TBI to warrant a hospital in-stay. Although hospital in-stays are more common in Europe for TBI, we assume this to be a function of the medical system and we have extrapolated our estimates for the rates of severe TBI to Europe, corresponding to approximately 500,000 patients per year. We assume a (WAC) pricing of $4,000 in the US and $3,000 in Europe. This pricing is approximately at parity with the total yearly reimbursement available from Medicaid for cognitive rehabilitation services (billed under the $1980 for physical therapy and speech-language pathology and $1980 for occupational therapy). We also assume 30% in discounts off the gross price in both territories. COGS are predicted at 8%, which includes the low single-digit royalty (modelled at 3%) due to Ramot for the technology. We have also included the $3.5m in milestones due to Ramot for Phase II completion, Phase III completion, and approval. Cost of selling is $5m per year in fixed costs, and 10% variable costs. Development costs for the program assume that patients will cost approximately $30,000 apiece, and that the company will need 370 patients between all trials. We forecast that the company will have exclusivity through the 2035 expiration of its patents.

Other changes to our valuation include lower net cash ($11.8m vs $14.5m), an increase in unallocated costs to reflect higher than expected SG&A expenses ($2.47m vs $1.79m), and advancing our NPVs to the current period. We expect to update our valuation with the release of interim data from the THX-TS01 Phase IIa trial expected in Q417 as well as potentially with the readout of the planned Phase I study of THX-ULD01, expected around YE17.

Exhibit 1: Valuation of Therapix

Development program	Region	Prob. of success	Launch year	Peak sales ($m)	Margin	rNPV ($m)
THX-TS01	US	10%	2021	177	55%	15.04
THX-TS01	Europe	10%	2021	120	55%	14.59
THX-TS01	Development costs					(2.41)
THX-ULD01	US	5%	2022	69	50%	2.72
THX-ULD02	Europe	5%	2022	106	57%	4.60
THX-ULD03	Development costs					(1.97)
Unallocated costs						(2.47)
Total						$30.1
Net cash and equivalents (H117) ($m)						$11.8
Total firm value ($m)						$41.9
Total ADS (m)						3.5
Value per ADS ($)						$11.98

Source: Edison Investment Research, Therapix reports

Financials

Therapix reported a loss of $2.5m for H117. This is a significant increase over H116 ($1.0m), albeit from a very low base and still low in absolute terms. The increase in spending was compounded by exchange rate losses of $0.7m. R&D spending for the period was $695,000, which was within our estimates ($1.2m for the year). SG&A spending significantly increased over our previous forecasts to $1.4m for the period, which is what we previously predicted for the year. This increase was attributed to more investor relations and business development activity. We have adjusted our SG&A forecasts in line with the current rate ($2.8m in 2017). This has increased our expected financing required to $27m ($12m in 2018, $15m in 2020) from $25m to reach profitability in 2021.

Exhibit 2: Financial summary

$000s	2016	2017e	2018e	2019e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	0.0	0.0	0.0	0.0
Cost of Sales	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0
R&D	739.0	1,140.0	4,500.0	9,000.0
SG&A	1,267.0	2,787.4	2,843.1	2,900.0
EBITDA	(1,675.0)	(3,572.4)	(6,988.1)	(11,545.0)
Normalised operating profit	(1,679.0)	(3,572.4)	(6,988.1)	(11,545.0)
Amortization of acquired intangibles	0.0	0.0	0.0	0.0
Exceptionals	7.0	0.0	0.0	0.0
Share-based payments	(327.0)	(355.0)	(355.0)	(355.0)
Reported operating profit	(1,999.0)	(3,927.4)	(7,343.1)	(11,900.0)
Net Interest	(6.0)	0.6	9.0	13.7
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	0.0	0.0	0.0	0.0
Profit Before Tax (norm)	(1,685.0)	(3,571.8)	(6,979.2)	(11,531.3)
Profit Before Tax (reported)	(2,005.0)	(3,926.8)	(7,334.2)	(11,886.3)
Reported tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(1,685.0)	(3,571.8)	(6,979.2)	(11,531.3)
Profit After Tax (reported)	(2,005.0)	(3,926.8)	(7,334.2)	(11,886.3)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	0.0	0.0	0.0	0.0
Net income (normalised)	(1,685.0)	(3,571.8)	(6,979.2)	(11,531.3)
Net income (reported)	(2,005.0)	(3,926.8)	(7,334.2)	(11,886.3)
Basic average number of ADS outstanding (m)	1	4	4	4
EPADS - basic normalised ($)	(1.80)	(0.97)	(1.81)	(2.85)
EPADS - diluted normalised ($)	(1.80)	(0.97)	(1.81)	(2.85)
EPADS - basic reported ($)	(2.14)	(1.07)	(1.90)	(2.94)
Dividend ($)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	441.0	11.0	11.0	11.0
Intangible Assets	0.0	0.0	0.0	0.0
Tangible Assets	11.0	11.0	11.0	11.0
Investments & other	430.0	0.0	0.0	0.0
Current Assets	804.0	10,098.8	15,400.4	4,243.6
Stocks	0.0	0.0	0.0	0.0
Debtors	117.0	0.0	0.0	0.0
Cash & cash equivalents	676.0	10,087.8	15,389.4	4,232.6
Other	11.0	11.0	11.0	11.0
Current Liabilities	(672.0)	(293.6)	(574.4)	(948.9)
Creditors	(672.0)	(293.6)	(574.4)	(948.9)
Tax and social security	0.0	0.0	0.0	0.0
Short term borrowings	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Long Term Liabilities	0.0	0.0	(12,000.0)	(12,000.0)
Long term borrowings	0.0	0.0	(12,000.0)	(12,000.0)
Other long term liabilities	0.0	0.0	0.0	0.0
Net Assets	573.0	9,816.2	2,837.0	(8,694.3)
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	573.0	9,816.2	2,837.0	(8,694.3)
CASH FLOW				
Op Cash Flow before WC and tax	(1,675.0)	(3,572.4)	(6,988.1)	(11,545.0)
Working capital	233.0	(261.4)	280.7	374.5
Exceptional & other	(38.0)	0.0	0.0	0.0
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(1,480.0)	(3,833.8)	(6,707.4)	(11,170.5)
Capex	(4.0)	0.0	0.0	0.0
Acquisitions/disposals	0.0	0.0	0.0	0.0
Net interest	0.0	0.6	9.0	13.7
Equity financing	913.0	12,900.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	(349.0)	0.0	0.0	0.0
Net Cash Flow	(920.0)	9,066.8	(6,698.4)	(11,156.8)
Opening net debt/(cash)	(1,596.0)	(676.0)	(10,087.8)	(3,389.4)
FX	0.0	345.0	0.0	0.0
Other non-cash movements	0.0	0.0	0.0	0.0
Closing net debt/(cash)	(676.0)	(10,087.8)	(3,389.4)	7,767.4

Source: Edison Investment Research, Therapix Biosciences reports

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