EDISON

Therapix Biosciences

Initiation of coverage

Tackling neurology with cannabinoids

Pharma & biotech

29 June 2017

Therapix is investigating the potential of new formulations of cannabinoids to address underserved diseases of the brain. It recently listed on NASDAQ in the US 2.3m ADS (worth $13.8m). The lead clinical program, THX-TS01, is currently in Phase II trials testing its potential for treating Tourette's in adults and THX-ULD01 is scheduled to begin Phase I trials for the treatment of mild cognitive impairment (MCI) in mid-2017. Both programs should qualify for a 505(b)(2) pathway to streamline approval. We arrive at an initial valuation of $38.4m or $10.97 per ADS.

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	(2.2)	(0.61)	0.0	N/A	N/A
12/18e	0.0	(5.6)	(1.44)	0.0	N/A	N/A
12/19e	0.0	(10.1)	(2.49)	0.0	N/A	N/A

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

THX-TS01: A potential Tourette's treatment

According to the National Institute of Neurological Disorders and Stroke, 200,000 people in the US suffer from Tourette syndrome, approximately one-third of whom are adults, which qualifies the program for an orphan drug designation from the FDA. Therapix expects to complete the single-arm, open-label 18 patient Phase IIa trials currently underway at Yale University in Q317. It also recently announced that an investigator sponsored Phase II placebo-controlled crossover study would commence at Hannover Medical School in Q317.

Leveraging the "entourage effect"

THX-TS01 is a combination of THC, the primary active ingredient in cannabis, and palmitoylethanolamide (PEA), a molecule generally regarded as safe (GRAS) and structurally similar to endocannabinoids. This product would be the first commercial formulation to explicitly test the entourage effect in the clinic, a theory that administration of multiple cannabinoids can increase their potency and effects.

THX-ULD01: Easing cognitive decline

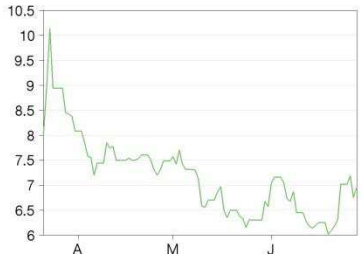
MCI is a symptom cluster that can afflict patients with early Alzheimer's disease, hypoxia or traumatic brain injury, among others. Therapix is investigating THX-ULD01, an ultra-low dose formulation of THC, as a treatment primarily for MCI. It is expected to undergo a Phase I study in Q217 to Q317, which should enable initiation of a Phase II clinical study around the end of the year.

Valuation of $38.4m or $10.97 per ADS

We arrive at an initial valuation of Therapix of $38.4m or $10.97 per ADS, based on a risk-adjusted NPV. Our initial probability of success for THX-TS01 is 10% based on the limited in human efficacy data. We currently do not value THX-ULD01, but will add it with more data on its path to market. We forecast that Therapix will need $25m in cash to reach approval in 2021.

Price	**US$6.96**
Market cap	**US$24m**
	NIS3.54/US$
Net cash ($m) estimated (December 2016 + offering)	14.5
ADS in issue	3.5m
Free float* *Company estimate	70%
Code	TRPX
Primary exchange	TASE
Secondary exchange	NASDAQ

Share price performance



%	1m	3m	12m
Abs	10.5	(17.6)	(13.2)
Rel (local)	9.4	(20.4)	(27.6)
52-week high/low	US$10.13		US$6.02

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	Q2-Q317
THX-TS01 Phase IIa data	Q417

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Edison profile page

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Investment summary

Company description: THC formulations for new indications

Therapix is a specialty pharmaceutical company that is developing cannabinoid based therapeutics for neurological disorders. It is developing THX-TS01 for Tourette syndrome and THX-ULD01 for mild cognitive impairment. THX-TS01 is a sublingual formulation of tetrahydrocannabinol (THC), the active constituent of cannabis, and palmitoylethanolamide (PEA), a generally regarded as safe lipid with cannabinoid properties. THX-TS01 is in a dose ranging, open-label Phase IIa clinical trial. THX-ULD01 is an ultra-low dose formulation of THC for the treatment of mild cognitive impairment associated with Alzheimer's or traumatic brain injury. THX-ULD01 is expected to enter a Phase I healthy volunteer study in Q217 or Q317.

Valuation: $38.4m or $10.97 per ADS

We arrive at an initial valuation of Therapix of $38.4m or $10.97 per ADS, based on a risk-adjusted NPV analysis. We currently only model THX-TS01 for the purpose of our valuation, although we expect to add THX-ULD01 when it enters the clinical phase and we have a clearer picture of its development pathway. We assign a 10% probability of success for THX-TS01 due to limited statistically significant clinical data in previous human trials, and the fact that it will need to outperform anti-hypertensives to command premium pricing (modelled at $54,000 in the US) We forecast almost $300m in peak sales, should the product gain approval in the US and Europe.

Financials: Recent NASDAQ IPO of $13.8m, runway into H218

Therapix's IPO on NASDAQ in March 2017 raised $13.8m gross (2.3m ADS at $6.00), which we estimate should provide a runway into H218. We expect operational losses to widen from $1.7m in 2016 to $2.2m in 2017 and $5.6m in 2018, with increasing R&D expenditures associated with the expanding clinical programs. We model the company requiring $25m in additional financing before approval in 2021 ($10m in 2018 and $15m in 2020). This is low for companies at this clinical stage on account of the expedited approval pathway.

Sensitivities: Clinical risk but streamlined pathway

The risks faced by Therapix are typical of developmental stage specialty pharma companies. It faces significant clinical risk due to the early stage of its development programs and the limited data to support the efficacy of its drugs. THX-TS01 has not been previously tested in humans for the treatment of Tourette's, although there are some data from other unaffiliated clinical trials of the potential of THC in the treatment of the disease that reached significance for some measures of tic severity. There is little evidence to support that the new co-formulation with PEA has increased efficacy, although it is unlikely to worsen the effects. The company will likely need to do a study to demonstrate that this co-formulation is superior to THC alone. However, the clinical pathway is significantly streamlined by seeking approval via the 505(b)(2) pathway, which allows the company to use data previously collected for the approvals of THC (as Marinol) to support approval. Moreover, trials for Tourette's are short at six to 10 weeks. We predict that this will translate into significant R&D savings. The company's other development program for THX-ULD01 is still in preclinical stages and currently the only data to support its development that has been published are from mice. A Phase I dosing study is expected to start in Q217 or Q317, although it will be in healthy volunteers. Finally, we expect the company to require $25m in additional financing before profitability in 2021, although this is lower than many other companies at the same stage, due to the low development costs.

Company description: Hope for neurological disease

Therapix is currently based in Tel Aviv and focuses on the development of drugs containing THC for the treatment of neurological disorders. The company is listed on the Tel Aviv stock exchange and NASDAQ and has previously raised over $40m.

In 2015, the company in-licensed the rights to drugs containing PEA from Dekel Pharmaceuticals (owned by Therapix Chairman Ascher Shmulewitz), which was used in combination with THC to develop THX-TS01 for the treatment of Tourette's. The company owes Dekel $375,000 in milestones and an 8% royalty on future sales of the product. The company has stated that it may also develop the drug for other potential indications such as antibacterial therapy and pain. THX-TS01 is currently in a Phase IIa dose ranging study, which is expected to produce results in H217.

In February 2016 the company in-licensed the technology related to ultra-low dose THC for the treatment of mild cognitive impairment from Ramot, the technology transfer company of Tel Aviv University. This technology was used in the formulation of THX-ULD01. THX-ULD01 is in preclinical development but a Phase I healthy volunteer study is planned for Q217 to Q317.

Exhibit 1: Therapix development programs

Product	Formulation	Stage	Notes
THX-TS01	Sublingual THC + PEA	Phase IIa	PEA Licensed from Dekel
THX-ULD01	Ultra-low dose THC	Preclinical	Licensed from Ramot

Source: Therapix BioSciences

Cannabinoids and the entourage effect

THC was isolated from cannabis in 1964 and identified as the main psychoactive component, although over 100 active compounds have subsequently been identified in the plant. THC was identified as a potent agonist of two novel receptors, cannabinoid receptor 1 (CB1) and cannabinoid receptor 2 (CB2). CB1 is expressed throughout the central nervous system and is implicated in the psychoactive effects of the drug, whereas CB2 is expressed throughout the body and has anti-inflammatory activity. The endogenous ligands of these receptors (so called endocannabinoids) are fatty acid amides and esters. In the brain, endocannabinoids mediate signalling between neurons outside of the canonical neurotransmitter systems and are important for modulating these cells' response to stimulus, promoting both long-term potentiation and depression in different regions. THC is currently approved in the US (under the original brand name Marinol and generic name dronabinol) to treat chemotherapy associated nausea and vomiting and anorexia associated with AIDS, and in a number of countries outside the US as a component of Sativex (a botanical extract of cannabis) for the treatment of spasticity due to multiple sclerosis.

One clinical property of cannabinoids that has been under investigation is the apparent potentiation of drug effects by other similar, but inactive compounds. This apparent property of cannabinoids has been termed the "entourage effect" and it occurs both in endocannabinoids and products of the cannabis plant. The term was coined in a 1998 paper co-authored by Therapix's scientific advisor Raphael Mechoulam when describing synergy between endocannabinoids.[1] The mechanism has been used to explain some of the subjective differences between the psychoactive effects of cannabis and synthetic THC. This effect has been hypothesized to be due to pharmacologic activity of the "inactive" component or an effect on drug metabolism based on structural similarities.[2]

[1] Ben-Shabat S, et al. (1998) An entourage effect: inactive endogenous fatty acid glycerol esters enhance 2-arachidonoyl-glycerol cannabinoid activity. *Eur. J. Pharacol.* 353, 23-31.

[2] Russo EB and McPartland JM (2003) Cannabis is more than simply Δ(9)-tetrahydrocannabinol. *Psychopharmacology* 165, 431-434.

However, it should be noted that these mechanisms fall within the description of normal drug interactions and do not constitute a unique property of cannabinoids.

THX-TS01 for Tourette syndrome

Therapix is currently developing THX-TS01 for the treatment of Tourette syndrome (TS). THX-TS01 is a sublingual formulation of THC and palmitoylethanolamide (PEA), a generally regarded as safe (GRAS) molecule. The drug is currently in a Phase IIa dose-ranging study in adults with moderate to severe TS. TS is a neuropsychiatric disorder characterized by repetitive involuntary movements and vocalizations called tics. TS is the most severe of a spectrum of tic disorders,[3] all of which are thought to be caused by abnormal activity of the neurotransmitter dopamine in the thalamus, basal ganglia, and frontal cortex. The disease is distinguished from other tic disorders based on the presence of multiple physical and at least one vocal tic, which vary in severity over time. Mild forms of the tic spectrum disorders, including mild forms of TS, may go undiagnosed, which leads to some variance in estimates of TS disease prevalence. The CDC estimates that 138,000 children are diagnosed with TS,[4] while the National Institute of Neurological Disorders and Stroke estimates that there are 200,000 children and adults with the disease.[5] The disease is much more common in children than adults, and almost always starts in childhood (6-12). By the time children reach age 18, 80-90% have had their tics reduced until they are mild and unlikely to require treatment.[6] However, adults with severe symptoms continue to face substantial social and professional obstacles. These prevalence rates qualify TS as an orphan disease for the purposes of orphan drug exclusivity in the US (seven years) and Europe (10 years).

Several scales are used to rate symptoms of Tourette's. Earlier studies use the Tourette Syndrome Global Scale (TSGS), although studies subsequently transitioned to the similar Yale Global Tic Severity Scale (YGTSS), although the two systems are similar in nature. Both scales are semi structured, clinician-rated assessments composed of three broad subgroups: physical tics (25% relative weight), vocal tics (25%), and functional impairment (50%). Patients described as having moderate TS symptoms range from 20-40 on both scales, and any score above 40 is considered severe.

Treatment options for TS

Approximately 80% of adult patients have mild enough symptoms that they can manage them without medication,[3] using therapy or other non-pharmacological means to minimize the impact TS has on the patient's life. Pharmacological treatment is typically necessary for patients with moderate and severe TS, which cripples their academic, social, and professional lives. Doctors typically begin treatment of TS with α_2 adrenergic agonists such as clonidine and guanfacine, which are more commonly used to treat hypertension. In those with moderate TS (mean TSGS 36), clonidine treatment led to a 12 point (26%) reduction in TSGS, compared to a 4 point decline for placebo treatment.[7] Guanfacine has similar efficacy to clonidine.[8] These improvements are modest, but these drugs remain the first line treatment because their adverse reactions are generally mild.

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3 Blocha M, et al (2011) Recent advances in Tourette syndrome. *Current Opinion in Neurology* 24, 119–125

4 Tourette Syndrome (TS), Data and Statistics. *Centers for Disease Control and Prevention.*

5 Tourette Syndrome Fact Sheet. *National Institute of Neurological Disorders*

6 Leckman J F, et al. (1998) Course of Tic Severity in Tourette Syndrome: The First Two Decades, *Pediatrics.* 102, 14-19.

7 Gaffeny G R, et al. (2002) Risperidone Versus Clonidine in the Treatment of Children and Adolescents With Tourette's Syndrome, *J. Am. Ac. Child Ad. Psych.* 41, 330-336.

8 Roessner V, et al. (2011) European Clinical Guidelines for Tourette Syndrome and Other Tic Disorders. Part II: Pharmacological Treatment. *Eur. Child Adolesc. Psychiatry* 20, 173-196.

If these fail, doctors resort to neuroleptics (also known as antipsychotics). Orap (pimozide), haloperidol, and Abilify (aripiprazole) have been FDA approved to treat tics, but several other neuroleptics are less commonly prescribed off label. However, neuroleptics have extensive and severe adverse effects,[9,10] the most common of which are sedation, sexual dysfunction, postural hypotension, and among atypical neuroleptics, weight gain and metabolic disorders. Additional rare but severe adverse effects include myocarditis, stroke, cardiac arrhythmia, sudden cardiac death, and Neuroleptic Malignant Syndrome (NMS), a potentially fatal neurologic disorder. These side effects can significantly affect the efficacy of their use, as one study employing haloperidol demonstrated: it failed to reach significant reduction in tics after 41% of patients had treatment limiting adverse events.[11]

An adverse effect of particular concern to TS sufferers is tardive dyskinesia, which is a movement disorder of its own caused by prolonged use of these drugs. Neuroleptics have high incidence rate for tardive dyskinesia ranging from 3-5% per year for younger individuals to up to 30% in the elderly.[12] Tardive dyskinesia can persist for years or decades and be severely debilitating, and the risk of causing it makes doctors reluctant to prescribe neuroleptics.

Recently some doctors have experimented with deep brain stimulation (DBS) for treatment resistant patients with TS.[13] While it may be effective, we expect the fact that it requires an electrode implanted in the brain to limit its use. In terms of recent drug developments, Otsuka Pharmaceutical's Abilify (aripiprazole) was approved to treat TS in children in 2014, and could be extended to treat TS in adults in the future. Abilify's efficacy was comparable to other neuroleptics, and in an FDA clinical trial the low dose demonstrated a reduction in symptoms measured by YGTSS of 46-54% (depending on dose, $p<0.002$).[14]

There are also several drugs in development to treat TS. Teva Pharmaceutical has recently completed Phase I clinical trials for Austedo (deutetrabenazine), a vesicular monoamine transporter 2 (VMAT2) inhibitor approved for chorea associated with Huntington's disease. Teva plans to enter Phase II clinical trials for pediatric TS patients late this year. Austedo appears comparable to neuroleptics in both efficacy and adverse effects.[15] The VMAT2 inhibitor Ingrezza (valbenazine, Neurocrine Biosciences) is approved for the treatment of tardive dyskinesia and is also in development for TS. However, in two recent studies in adults and in children, Ingrezza failed to demonstrate a statistically significant change in YGTSS. Ingrezza did demonstrate symptom improvement according to the Clinical Global Impression of Change scale and Neurocrine is moving forward with clinical trials for the drug. Furthermore Ingrezza has only moderate side effects compared to neuroleptics,[16] although they are noticeably worse than THC and anti-hypertensive drugs. The more severe side effects are fall, balance disorder, vomiting, nausea, arthralgia, respiratory infections, dyskinesia, and extrapyramidal symptoms (non-akathisia). Considering the lack of treatments for TS, if Ingrezza or Austedo are approved for TS in children, off-label use in adults is a strong possibility.

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9 Üçok, A and Gaebel W (2008) Side Effects of Atypical Antipsychotics: A Brief Overview. *World Psychiatry* 7, 58-65.

10 Muench J and Hamer AM (2010) Adverse Effects of Antipsychotic Medications. *American Family Physician* 81, 617-622.

11 Sallee F R, et al. (1997) Relative Efficacy of Haloperidol and Pimozide in Children and Adolescents With Tourette's Disorder. *Am. J. Psychiatry* 154, 1057–1062.

12 Waln O and Jankovic J, (2013) An Update on Tardive Dyskinesia: From Phenomenology to Treatment. *Tremor and Other Hyperkinetic Mov* 3: tre-03-161-4138-1.

13 *Deep Brain Stimulation: A New Option for Tourette Syndrome*. Tourette Association of America,

14 Abilify label and ClinicalTrials.gov Identifier: NCT01727700

15 Jankovic J, et al. (2016) Deutetrabenazine in tics associated with Tourette syndrome. *Tremor Other Hyperkinet Mov.* 6. Supplement P1.046.

16 Ingrezza FDA label, and Ingrezza prescribing information.

Exhibit 2: Competing TS drugs

Drug	Sponsor or Owner	Stage	Efficacy	Side effects
Clonidine	Generic	Not in trials	Mean 26% reduction in TSGS (p<0.0001)[7]	Mild
Guanfacine	Generic, also branded as Intuniv	Not in trials	Unclear, likely less than clonidine	Mild
Pimozide	Generic Branded as Orap by Teva	FDA approved	average 40% reduction in TSGS (p=0.02)[11]	Severe
Haloperidol	Generic	FDA approved	average 27% reduction in TSGS (p=n.s)[11]	More severe than Pimozide
Risperidone	Generic	Not in trials	33% mean reduction in YGTSS (p<0.01 vs b.l.)[17]	Less severe than Pimozide
Abilify	Otsuka Pharmaceutical, and new generics	FDA approved	46-54% mean reduction in YGTSS (p<0.002)[14]	Severe
THC	Various	Pilot studies	22% mean reduction in YGTSS (p=0.13)[18]	Mild

Source: Roessner V, et al.,[8] various. Notes: TSGS=Tourette Syndrome Global Scale, YGTSS=Yale Global Tic Severity Scale, b.l.=baseline

Exhibit 3: Drugs currently in development for TS

Product	Company	Stage	Notes
Ingrezza	Neurocrine	Phase IIb	Vesicular monoamine transporter 2 (VMAT2) inhibitor. 12 point reduction of YGTSS, not statistically significant. Moderate side effects
Austedo	Teva Pharmaceutical	Phase II starting late this year	Vesicular monoamine transporter 2 (VMAT2) inhibitor. Mean 37% reduction in YGTSS in a pilot study,[15] severe side effects
CPP-115	Catalyst Pharmaceuticals	Phase II	Gamma-aminobutyric acid (GABA) aminotransferase inhibitor
Ecopipam	Psyadon Pharmaceuticals	Phase II	Dopamine D1 & D5 antagonist
SNC-102 (acamprosate calcium)	Synchroneuron	Phase II	Gamma-aminobutyric acid (GABA) agonist
Guanfacine & Amphetamine	Genco Sciences	Phase I	Dopamine D1 & D5 antagonist

Source: Evaluate Pharma, various

THC as a Tourette syndrome treatment

Two small-scale randomised, controlled clinical studies have been performed examining THC for the treatment of Tourette's. The first study[18] was a randomised crossover trial of 12 individuals, and it showed a 22% improvement in YGTSS, although it did not reach statistical significance. However a statistical improvement was seen for complex motor tics (p=0.015) and for patient reported symptoms (p=0.015). The second study examined 24 patients in placebo and dose escalation cohorts (ranging from 2.5mg to 10mg of THC per day). It reached similar results, showing improvement in symptom ratings of motor tics (p=0.04) and patient reported symptoms (p<0.05), but failed to reach statistical significance in the overall YGTSS.[19] Both of these studies were sponsored in part by Therapix Scientific Advisor Kirsten Müller-Vahl. These early clinical studies and THC's effective treatment of spasticity[20] lead Therapix to believe THC maybe an effective treatment for TS. For the therapeutic doses used in these studies, THC caused only mild side effects. However, anxiety and restlessness did force one patient to drop out of the 24 person study.

17 Kim BN, et al. (2005) Effectiveness and Safety of Risperidone for Children and Adolescents with Chronic Tic or Tourette Disorders in Korea. *Adol. Psychopharm.* 15, 318-324.

18 Müller-Vahl KR (2002) Treatment of Tourette's Syndrome with Δ9-Tetrahydrocannabinol (THC): A Randomized Crossover Trial. *Pharmacopsychiatry* 35, 57-61.

19 Müller-Vahl KR et al. (2003) Delta 9-Tetrahydrocannabinol (THC) is Effective in the Treatment of Tics in Tourette Syndrome: a 6-Week Randomized Trial. *J. Clin. Psychiatry* 64, 459-465.

20 Koppel BS, et al. (2014) Systematic review: Efficacy and safety of medical marijuana in selected neurologic disorders *Neurology* 82, 17, 1556–1563.

THC, PEA, and the THX-TS01 clinical trial

Unlike earlier attempts to target Tourette's using THC, THX-TS01 is a co-formulation of THC with the GRAS molecule PEA, a lipid amide present in food that shares significant structural similarity to endocannabinoids. PEA has been approved for use as a health supplement in some parts of Europe and Canada because small-scale clinical studies,[21] as well as case studies,[22] indicate some benefit for the treatment of chronic inflammation and chronic pain, as well as little-to-no side effects. However, the documented anti-inflammatory and anti-nociceptive properties of PEA do not suggest that it will be an effective treatment for TS. PEA does not address the abnormal activity of dopamine, which is believed to cause TS. Therapix believes that the entourage effect will enable PEA to enhance the potency of THC and improve its formulation's overall efficacy, although this is by no means guaranteed. The intellectual property surrounding this formulation centres on the addition of PEA to THC for the purposes of the entourage effect (filed in 2016), although we expect the primary protection to come from orphan drug designation (seven years in the US and 10 years in the EU). The drug will need to perform at least as well as the anti-hypertensive drugs (26% reduction in symptoms in previous trials) to have a viable market and secure reimbursement. However, we expect a relatively benign adverse effect profile, which should enable it to compete as an earlier-line treatment than neuroleptics.

THX-TS01 is currently in a single-arm open-label Phase IIa clinical trial being conducted in partnership with Yale University in adults patients with TS. 18 subjects with significant tic symptoms (YGTSS>22) and stabilised with their current treatment regimen will receive one daily treatment of THX-TS01 via oral administration and will be followed-up for a period of 12 weeks. All patients will be given 400mg of PEA for the duration of the trial, and the dose of THC will gradually be increased up to 10mg during the first week, and will remain at that level for the duration of the trial unless adverse effects occur. This trial is projected to end in early Q317 and have data in Q417. Therapix also plans to conduct an investigator initiated study led by Professor Kirsten Müller-Vahl and in partnership with the Hanover Medical School, a leading centre of cannabinoid medical research. The cross-over proof-of-concept study will be randomised, double-blind and placebo controlled, and will enrol 20 patients to evaluate the safety, tolerability and efficacy of up to twice daily oral THX-TS01 in treating adults with TS. This trial is expected to begin in Q317 and last 26 weeks (13 weeks on each arm). If current clinical trial results are favourable, Therapix plans to begin larger Phase IIb clinical trials in Q417. We expect future clinical trials to have a shorter duration, as safety has been established (via the approval of Marinol and the GRAS status for PEA) and previous approvals have been on the basis of trials six to 10 weeks in duration. Therapix has applied for orphan drug designation from the FDA (with a response expected in September 2017), which would qualify the drug for seven years of market exclusivity after approval.

THX-ULD01 for mild cognitive impairment

Therapix is developing THX-ULD01 and an ultra-low dose formulation of THC for the treatment of mild cognitive impairment (MCI). It is currently in preclinical studies but has announced that it will be progressing to a Phase I study in healthy volunteers in mid-2017. This clinical trial will measure the pharmacokinetics and bioavailability of this ultra-low dose formulation, and it plans to initiate a Phase IIa open-label study in MCI patients in Q417.

MCI is a term that was coined to describe some of the early symptoms of Alzheimer's disease, but certain other disease etiologies can produce similar effects. These other causes of cognitive

[21] Gabrielsson L, et al. (2016) Palmitoylethanolamide for the treatment of pain: pharmacokinetics, safety and efficacy. *Brit. J. Clin. Pharm.* 82, 932-942.

[22] Keppel J M, et al. (2012) Therapeutic utility of palmitoylethanolamide in the treatment of neuropathic pain associated with various pathological conditions: a case series. *J. Pain. Res*. 5, 437–442.

impairment include both cerebral damage (such as traumatic brain injury or hypoxia) as well as other forms of dementia (such as dementia with Lewy bodies). Diagnostically, MCI is defined as a deficiency in one or more of the core cognitive domains that does not rise to the level of an impact on independence. The four core cognitive domains are short-term memory, language, visuospatial ability, and executive function such as planning and abstract reasoning.

MCI associated with Alzheimer's

Although MCI is associated with Alzheimer's, it is important to note that it has a unique pathology and clinical presentation. MCI can be differentiated clinically from Alzheimer's and cognitive declines due to ageing on an array of different rating scales.[23] However, approximately 16% of patients with MCI progress to Alzheimer's per year.[24] The precise reason why the early stages of Alzheimer's are associated with MCI is poorly understood. Alzheimer's is a neurodegenerative disease characterised by the loss of neurons in the cerebral cortex. There also appears to be a neurodegenerative aspect of MCI and previous studies have identified a loss of cholinergic neuron from the nucleus basalis of Meynert.[25] However, the degree to which Alzheimer's related pathologies such as the accumulation of beta-amyloid plaques or the formation of neurofibrillary tangles are associated with neuronal loss or symptoms is unknown, as in the case for Alzheimer's itself. In addition to the neurodegenerative component, the brains of individuals diagnosed with MCI also show a high frequency of vascular disease, and both ischemic lesions and infarctions in the cerebral microvasculature are common.[26] MCI in the elderly is common with an estimated prevalence of between 3% and 19% in patients over 65.[27]

There are currently no medications approved directly for the treatment of MCI associated with Alzheimer's, although drugs used to treat Alzheimer's such as donepezil may be prescribed. Additionally, physicians may prescribe medication to treat other disorders such as hypertension and depression that are known to have an impact on cognition. The development of agents to treat MCI is generally in trials that also include Alzheimer's patients, and there are currently nine ongoing clinical trials that we have identified explicitly enrolling patients with MCI. It should be noted that other Alzheimer's trials may include patients on this part of the disease spectrum (although not explicitly stated) as the goal of these studies is typically to enrol patients as early as possible, and that any future approvals in this space may become widely used for MCI. The lead development programs are beta secretase cleaving enzyme (BACE) inhibitor Elenbecestat and Verubecestat. These drugs aim to reduce the concentration of beta amyloid plaques by inhibiting the enzyme that generates the Aβ protein. Both of these programs have primary endpoints of change in Clinical Dementia Rating - Sum of Boxes (CDR-SB) score after two years of treatment. Both these agents previously showed the capacity to reduce the concentration of Aβ. However, Merck halted its Phase III study Verubecestat in patients with mild to moderate Alzheimer's disease in February 2017 due to futility, so there is some question regarding the efficacy of these agents.

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[23] Grundman M, et al. (2004) Mild Cognitive Impairment Can Be Distinguished From Alzheimer Disease and Normal Aging for Clinical Trials. *J. Am. Med. Assoc. Neurol.* 61, 59-66.

[24] Petersen RC, et al. (2005) Vitamin E and donepezil for the treatment of mild cognitive impairment. *N. Engl. J. Med.* 352, 2379–2388.

[25] Mufson EJ, et al. (2000) Loss of nucleus basalis neurons containing trkA immunoreactivity in individuals with mild cognitive impairment and early Alzheimer's disease. *J. Comp. Neurol.* 427, 19–30.

[26] O'Brien JT, et al. (2003) Vascular cognitive impairment. *Lancet Neurol.* 2, 89–98.

[27] Gauthier S, et al. (2006) Mild cognitive impairment. *Lancet* 367, 1262-1270.

Exhibit 4: MCI associated with Alzheimer's clinical programs

Product	Company	Stage	Notes
Elenbecestat	Eisai/Biogen	Phase III	Beta secretase cleaving enzyme (BACE) inhibitor
Verubecestat	Merck	Phase III	Beta secretase cleaving enzyme (BACE) inhibitor
Pioglitazone	Takeda	Phase III	Approved for type 2 diabetes
ABBV-8E12	AbbVie	Phase II	Anti-tau antibody
Oxybutynin	Pfizer	Phase II	Approved for incontinence
Fesoterodine	Pfizer	Phase II	Approved for overactive bladder
PQ912	Probiodrug	Phase II	Glutaminyl cyclase inhibitor
LY3303560	Eli Lilly	Phase I	Ketogenic agent
LY3002813	Eli Lilly	Phase I	Anti-A-beta antibody
TAK-071	Takeda	Phase I	Muscarinic agonist

Source: Evaluate Pharma, ClinicalTrials.gov

MCI associated with traumatic brain injury

MCI as a result of traumatic brain injury (TBI) is also mediated by the death of neurons and damage to the microvasculature of the brain. Regions of cell death are readily identifiable in the brains of individuals following TBI, both with and without concomitant internal bleeding.[28] The initial physical insult to the brain is followed by an inflammatory cascade that can exacerbate damage.[29] TBI is common and Centers for Disease Control and Prevention estimates that it was responsible for approximately 2.5 million emergency room visits and approximately 300,000 hospital in-stays in the US per year.[30] However, there may be a much higher rate of unreported TBI and there may be as many as 1.6m to 3.8m TBI associated with sports activities alone in the US. Approximately 37% of patients admitted to a hospital for TBI have long lasting disability following the event.[31]

There are also no approved medications for cognitive impairment following TBI, although there are a large number of development programs. There are no less than 14 ongoing clinical programs, and over 50 preclinical programs, by our estimation. The therapies in development are largely anti-inflammatories and stem cells (which have potent anti-inflammatory properties) and therefore have the potential to limit damage from the neuroinflammatory stage. The most advanced clinical program is VAS203 from Vasopharm in Phase III. The product is an inhibitor of inducible nitric oxide synthase, aimed at reducing inflammation and edema following the brain injury. In a 32 person Phase IIa study VAS203 significantly reduced the level of therapy needed to stabilise patients in the week following injury ($p<0.04$). In an off-protocol analysis, it significantly improved patient outcomes as measured on the extended Glasgow Outcome Score (eGOS, $p<0.01$), indicating that the compound has the potential to affect long-term cognitive outcomes.[32] The estimated primary completion date of the Phase III study is November 2018.

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Exhibit 5: TBI clinical programs

Product	Company	Stage	Notes
VAS203	Vasopharm	Phase III	Nitric oxide synthase (NOS) inhibitor
CEVA101	Fortress Biotech	Phase II	CNS cell therapy
ISC-hpNSC	International Stem Cell	Phase II	Neuronal stem cell therapy
Trofinetide Oral	Neuren Pharmaceuticals	Phase II	Insulin-like growth factor 1 (IGF-1) analogue
SB623	SanBio	Phase II	Mesenchymal cell therapy
Stemedyne-MSC	Stemedica Cell Technologies	Phase II	Cardiac stem cell therapy
VOLT02	Levolta Pharmaceuticals	Phase II	Conjugated progesterone
NeuroSTAT	NeuroVive Pharmaceutical	Phase II	Cyclosporine A
Cirara	Remedy Pharmaceuticals	Phase II	NC Ca-ATP channel inhibitor
BQ-A	Bioquark	Phase I	Tissue repair agent
Lpathomab	Apollo Endosurgery	Phase I	Anti-lysophosphatidic acid (LPA) MAb
MAP4343	Mapreg	Phase I	Microtubule associated protein (MAP) 2 inhibitor
Plasma Gelsolin	BioAegis Therapeutics	Phase I	Anti-inflammatory
NeuroAiD	Moleac	Phase I	Neuroprotectant

Source: Evaluate Pharma

Cannabinoids and cognitive impairment

There has been significant investment into research regarding the relationship between cannabinoids and cognitive ability. However, the majority of this research has focused on cannabis abuse and the general consensus is that cannabinoids have a chronic negative impact on cognition. Long-term cannabis users test significantly lower on measures of learning and memory than short-term users and control subjects,[33] and these results have been replicated in multiple studies.[34]

However, contrary to these observations, there are a number of early stage studies (primarily in mice) that cannabinoids can be neuroprotective. For instance, cannabinoids reduced the generation of pro-inflammatory cytokines following TBI in mice.[35] Interestingly however, the action of THC on CB1 appears to mediate some of its neuroprotective effects, suggesting that some of the anti-inflammatory mechanisms of the drug are specific to brain tissue.[36] This neuroprotective effect can be induced with ultra-low doses of THC orders of magnitude lower than the psychoactive dose. Cannabinoids also appear to have an impact on the progression of Alzheimer's disease in mice. In one study, oral cannabinoids both reduced neuroinflammation and reduced the deposition of amyloid plaques in a mouse model of the disease.[37]

The logic behind developing ultra-low dose THC for the treatment of MCI is that at this level the anti-inflammatory and neuroprotective effects dominate, and that the long-term impairment in cognition in cannabis abusers is from prolonged alterations in cognition. However, there is some research that suggest that even these ultra-low doses can produce long-lasting deficits in cognition.[38]

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Sensitivities

Therapix faces significant clinical and commercial risks before it can achieve sustained profitability. The company's lead program, THX-TS01, is in a very early clinical stage and is previously untested in humans, and therefore carries the typical clinical development risks for a product in this stage of development. However, there is some in human data to support the use of THC for the treatment of Tourette's. Additionally, Sativex (which includes THC) has been approved in a number of countries for the treatment of spasticity associated with multiple sclerosis, so there is some support for the use of THC in movement disorders, albeit one with a very different etiology. Previous clinical trials of THC for the treatment of TS failed to reach statistical significance for the approval endpoint of improvement in YGTSS, although they did reach significance for specific subsets of symptoms. There have not been any previous clinical trials of the THX-TS01 formulation containing PEA, and therefore the extent of entourage effect in this combination is unknown. The company will have to demonstrate to the FDA and EMA that this combination improves the drug's effect above and beyond the approved generic THC formulation, which will make future trials more difficult. This is offset by the fact that the company is seeking approval through the 505(b)(2) pathway, which will allow the company to seek approval using safety data from the previously approved THC formulations.

If THX-TS01 is able to achieve approval, we expect it to face a series of commercial hurdles as well. There is significant pressure to set a high price for the drug given the limited patient population. However, we expect significant payer pushback as the drug is very similar to the approved generic dronabinol and the current standard of care for Tourette's is driven by low priced generics. The clinical benefit must be unambiguous to support widespread adoption.

The company's other active development program for THX-ULD01 currently has not entered the clinic and there is essentially no in human data at this time. The company has a planned Phase I clinical trial, although it will be in healthy volunteers and will not have an efficacy readout. The drug could potentially be developed for MCI associated with the onset of Alzheimer's or TBI. The market for the former case is very large, but there are no approved drugs in the space and Alzheimer's itself is littered with high-profile drug failures. Moreover, the clinical development for MCI associated with Alzheimer's would require thousands of patients given small expected treatment effects. By comparison the development for TBI should be easier, and require fewer patients.

Finally, the company faces financing risks similar to other pre-profit pharmaceutical companies, and we expect it to require $25m in additional financing before profitability in 2021. However, we should note that this is lower than many other similar companies, largely due to the cost mitigation associated with approval via the 505(b)(2) pathway.

Valuation

We arrive at an initial valuation of Therapix of $38.4m or $10.97 per ADS, based on a risk-adjusted NPV analysis using a 12.5% discount rate (our standard rate for clinical stage companies). We currently only value the company based on the THX-TS01 program for TS in adults, because THX-ULD01 has not entered the clinic and we have significantly less information on its intended clinical pathway, although we expect to update this in the future.

Our probability of success for THX-TS01 is 10%. There have been two placebo controlled clinical studies of THC for the treatment of TS, both of which failed to reach statistical significance in improvement on the YGTSS, which is the approvable endpoint for TS. The reports of efficacy using THC or cannabis for the treatment of TS are largely anecdotal. The recent failure of the clinical trials of Ingrezza highlight some of the difficulties in developing drugs for this indication, despite the drug having proven efficacy in movement disorders. However, the sublingual formulation of THC in THX-TS01 may improve bioavailability and efficacy of the drug. The drug will have to perform at least as well as anti-hypertensives to have a viable market, although we believe that the safety and adverse event profile will attractively position the drug compared to neuroleptics.

We expect the clinical pathway for THX-TS01 to be low cost by many measures. The 505(b)(2) pathway enables smaller trials and fewer preclinical requirements. Additionally, we expect the price per patient to be small because trials for TS are typically short, at approximately six to 10 weeks. We currently model a price per patient in the clinical trials of $20,000. We expect the company to begin marketing in 2021 and have market exclusivity for seven years in the US and 10 years in Europe from orphan drug designations.

Our estimated target market for THX-TS01 is adult TS patients with severe symptoms requiring treatment, which we estimate at approximately 7,600 individuals in the US and 12,600 in Europe (2.3 per 100,000). This is derived from estimated CDC childhood prevalence (1/360) adjusted for disease progression into adulthood (10-20%) and need for medication (15%). We predict a penetration into this market reaching 20%, hindered by the availability of low-cost generics.

We expect the company to seek premium pricing for the drug (compared to the available generics) given the small target market. There is some pricing pressure from the availability of generic dronabinol as well as other approved and off-label TS medications. However, we believe that an effective and safe drug in this space can command a premium as the small market of adult TS patients that need management translates to a small increase in the cost per cover life to payers. Our estimated target price at launch is $54,000 in the US and $49,000 in Europe. Our European pricing is discounted less than other products because of increased price support in the region for orphan drugs.

We include COGS of approximately 13%, which includes the 8% royalty payable to Dekel. Our cost of selling is forecast to be low ($1m per region overhead and 5% variable costs) because the target market is small, already integrated into the medical system, and has significant patient support networks.

We expect to update our valuation following data from the ongoing Phase IIa clinical trial expected in Q417. Additionally, we may update our valuation when THX-ULD01 enters the clinic (expected in Q217) and when we learn more information regarding its clinical program.

Exhibit 6: Valuation of Therapix

Development program	Region	Probability of success	Launch year	Peak sales ($m)	Margin	rNPV ($m)
THX-TS01	US	10%	2021	177	55%	14.18
THX-TS01	Europe	10%	2021	120	55%	13.76
THX-TS01		Development costs				(2.32)
Unallocated costs						(1.79)
Total						$23.8
Net cash and equivalents (YE16 + offering) ($m)						$14.5
Total firm value ($m)						**$38.4**
Total shares (m)						3.5
Value per share ($)						**$10.97**

Source: Therapix BioSciences reports, Edison Investment Research

Financials

Therapix had normalized operating losses of $1.7m for 2016, which we expect to substantially increase over coming periods as it expands its clinical programs. The company previously did not have any ongoing clinical trials, and thus we do not believe these prior periods are predictive of future spending. We expect the operating loss to rise to $2.2m in 2017 and $5.6m in 2018, driven by R&D expenditures of $1.2m and $4.5m, respectively. We currently model SG&A spending to remain steady over this period at approximately $1.4m, although this may change in response to any regulatory concerns. We currently predict that the company will become profitable in 2021 with the launch of THX-TS01. The company recently listed on NASDAQ, raising an estimated $13.8m gross (2.3m ADS at $6.00), which we forecast will provide a runway into H218. We model that it will require an additional $25m in financing to reach approval and profitability in 2021 ($10m in 2018 and $15m in 2020), which is low for a company at this stage of development.

Exhibit 7: Financial summary

$'000s	2016	2017e	2018e	2019e
31-December	IFRS	IFRS	IFRS	IFRS
INCOME STATEMENT				
Revenue	0	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	0	0	0
R&D	739	1,200	4,500	9,000
SG&A	1,267	1,403	1,431	1,460
EBITDA	(1,675)	(2,248)	(5,576)	(10,105)
Normalised operating profit	(1,679)	(2,248)	(5,576)	(10,105)
Amortisation of acquired intangibles	0	0	0	0
Exceptionals	7	0	0	0
Share-based payments	(327)	(355)	(355)	(355)
Reported operating profit	(1,999)	(2,603)	(5,931)	(10,460)
Net Interest	(7)	1	11	15
Joint ventures & associates (post tax)	0	0	0	0
Exceptionals	0	0	0	0
Profit Before Tax (norm)	(1,686)	(2,248)	(5,566)	(10,090)
Profit Before Tax (reported)	(2,005)	(2,603)	(5,921)	(10,445)
Reported tax	0	0	0	0
Profit After Tax (norm)	(1,686)	(2,248)	(5,566)	(10,090)
Profit After Tax (reported)	(2,005)	(2,603)	(5,921)	(10,445)
Minority interests	0	0	0	0
Discontinued operations	0	0	0	0
Net income (normalised)	(1,686)	(2,248)	(5,566)	(10,090)
Net income (reported)	(2,005)	(2,603)	(5,921)	(10,445)
Basic average number of ADS outstanding (m)	1	4	4	4
EPADS - basic normalised ($)	(1.80)	(0.61)	(1.44)	(2.49)
EPADS - diluted normalised ($)	(1.80)	(0.61)	(1.44)	(2.49)
EPADS - basic reported ($)	(2.14)	(0.71)	(1.54)	(2.58)
Dividend ($)	0	0	0	0
BALANCE SHEET	**0**	**0**	**0**	**0**
Fixed Assets	441	12	12	12
Intangible Assets	0	0	0	0
Tangible Assets	11	12	12	12
Investments & other	430	0	0	0
Current Assets	804	11,880	16,588	6,870
Stocks	0	0	0	0
Debtors	117	0	0	0
Cash & cash equivalents	676	11,868	16,575	6,857
Other	11	12	12	12
Current Liabilities	(672)	(185)	(458)	(831)
Creditors	(672)	(185)	(458)	(831)
Tax and social security	0	0	0	0
Short term borrowings	0	0	0	0
Other	0	0	0	0
Long Term Liabilities	0	0	(10,000)	(10,000)
Long term borrowings	0	0	(10,000)	(10,000)
Other long term liabilities	0	0	0	0
Net Assets	573	11,708	6,142	(3,948)
Minority interests	0	0	0	0
Shareholders' equity	573	11,708	6,142	(3,948)
CASH FLOW	**0**	**0**	**0**	**0**
Op Cash Flow before WC and tax	(1,675)	(2,248)	(5,576)	(10,105)
Working capital	234	(418)	274	372
Exceptional & other	(38)	0	0	0
Tax	0	0	0	0
Net operating cash flow	(1,480)	(2,667)	(5,303)	(9,733)
Capex	(4)	0	0	0
Acquisitions/disposals	(0)	0	0	0
Net interest	0	1	11	15
Equity financing	913	13,800	0	0
Dividends	0	0	0	0
Other	(349)	0	0	0
Net Cash Flow	(920)	11,134	(5,292)	(9,718)
Opening net debt/(cash)	(1,596)	(676)	(11,868)	(6,575)
FX	0	58	0	0
Other non-cash movements	0	0	0	0
Closing net debt/(cash)	(676)	(11,868)	(6,575)	3,143

Source: Therapix BioSciences reports, Edison Investment Research

Contact details	Revenue by geography
Therapix Biosciences Azrieli Center (Square Tower) Floor 27 Tel Aviv 6702501 Israel +972 3 6167055 http://therapixbio.com/	N/A

Management team

Chief Executive Officer: Elran Haber	Chief Technology Officer: Dr Adi Zuloff-Shani
Dr Haber has served as Therapix's CEO since November 2015. Previously, he had served as the company's VP of Business Strategy and Innovation, beginning in March 2014. Dr Haber spent more than 10 years as chairman and board member of several privately held, and publicly traded, companies including Issta Lines (TASE: ISTA) from 2007 to 2012, American Express Global Business Travel - Israel (Histour-Eltive) from 2010 to 2012, and has been a member of various board committees. He has served in senior executive roles in various life science companies and a private investment firm. Dr Haber holds a PhD in Pharmaceutical Science and an MBA in Finance & Financial Engineering, both from the Hebrew University of Jerusalem, Israel.	Dr Zuloff-Shani joined Therapix in 2017 and brings more than 15 years of experience as an R&D executive to her role as chief technology officer. From 2012 until 2016, Dr Zuloff-Shani served as a vice president of development at Macrocure (NASDAQ: MCUR) where, aside from leading all research and development activities, she interacted with and was involved with the activities of all departments including clinical, operations, quality assurance, quality control, finance and regulatory affairs. Prior to that, Dr Zuloff-Shani spent eight years as the senior scientist in the research & development unit of Magen David Adom's National Blood Services. Dr Zuloff-Shani holds a PhD in human biology and immunology from Bar-Ilan University, Israel.
Chief Financial Officer: Josh Blacher	**Chairman of the Board of Directors: Dr Ascher Shmulewitz**
Mr Blacher joined Therapix in 2017, bringing with him more than nine years' experience in biotech-related financial management, business development, investing and operations. Before joining Therapix, Mr Blacher was the CFO for Galmed Pharmaceuticals, and earlier served as director of business development at Teva Innovative Ventures, Teva Pharmaceuticals' early and mid-stage investment and in-licensing arm. In that capacity, he helped build and manage Teva's portfolio of approximately 20 equity investments in biotech entities. Before becoming involved in biotech, he worked in capital markets for 14 years, holding positions at Deutsche Asset Management, Morgan Stanley and Lehman Brothers.	Dr Shmulewitz is a serial entrepreneur and angel investor in biomedical technologies. Dr Shmulewitz served in senior executive positions at Advanced Technology Laboratories and has been director of Therapix since 21 February 2013. He has originated over two dozen life science companies and has led 14 of these companies to successful exits in less than a decade, mostly through M&A transactions with large medical device companies. Currently, Dr Ascher Shmulewitz also serves as a co-founder and chief technology officer at Foodlab Capital.

Principal shareholders	(%)
HS Contrarian Investments LLC	3.89%
Stetson Capital Investments Inc	1.50%
Morgan Staley	0.71%
KCG Holdings Inc	0.32%

Companies named in this report

AbbVie (ABBV); Apollo Endosurgery (APEN); Biogen (BIIB); Catalyst Pharmaceuticals (CPRX); Eisai (TYO:4523); Eli Lilly (LLY); Fortress Biotech (FBIO); Johnson & Johnson (JNJ); Merck (MRK); Neuren Pharmaceuticals (ASX:NEU); Neurocrine (NBIX); Otsuka (TYO:4578); Pfizer (PFE); SanBio (TYO:4592); Takeda (TYO:4502); Teva (TEVA)

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