EDISON

Tonix Pharmaceuticals

Development

Time to execute

Pharma & biotech

With the commencement of enrolment for the pivotal Phase III HONOR study of TNX-102 SL in military-related post-traumatic stress disorder (PTSD), the future of Tonix is squarely in its hands. The study is expected to enroll up to 550 patients with a CAPS-5 of ≥33 upon entry. Importantly, the FDA has agreed to an interim analysis encompassing 275 patients at which point it may be stopped for efficacy. The FDA has also indicated that if the data are "statistically persuasive" only one study may be needed for approval. The interim analysis is expected in H118 with full data in H218.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS (c)	P/E (x)	Yield (%)
12/15	0.0	(48.1)	(28.62)	0.0	N/A	N/A
12/16	0.0	(38.8)	(15.41)	0.0	N/A	N/A
12/17e	0.0	(24.6)	(3.68)	0.0	N/A	N/A
12/18e	0.0	(26.9)	(3.87)	0.0	N/A	N/A

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

Data in 2018

The HONOR study began enrolling patients in Q117 with an interim analysis encompassing 275 patients (50% of the 550 total expected). The trial may be stopped after the interim analysis for efficacy (though the exact statistical hurdle rate has not been disclosed), the sample size adjusted or the study continue as planned. The interim analysis is expected in H118 with full data in H218.

Need for only one Phase III is possible

The company has reported that during the initial cross-disciplinary breakthrough meeting with the FDA, the agency indicated that if HONOR study data are "statistically persuasive" then it is possible that Tonix would not need to run a second Phase III for approval. This hurdle rate has not been disclosed, but we would expect a p-value of p<0.01, more significant than the standard p<0.05.

Potential FDA approval in 2019

Due to the granting of breakthrough therapy designation (BTD), the approval application for TNX-102 SL is eligible for priority review, which may mean a six-month instead of a 10-month review period. Coupled with the potential for the HONOR study to be halted for efficacy at the interim analysis in H118, approval is possible in 2019. However, we continue to project approval in 2020.

Valuation: $235m or $31.46 per basic share

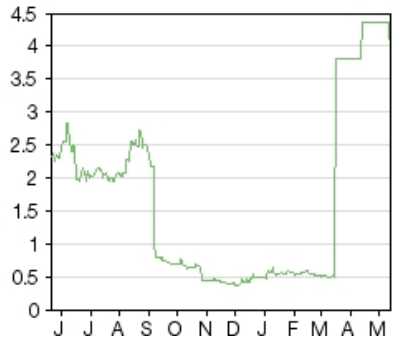
We have adjusted our valuation from $236m or $31.57 per basic share to $235m or $31.46 per basic share. The change in valuation is mostly due to a lower cash balance, mitigated slightly by lower R&D spending assumptions for the PTSD program. We expect a funding requirement of $85m before profitability in 2023, down from $110m previously, due to the significant control of expenses. Tonix appears to be fully funded into H218.

19 May 2017

Price	**US$4.11**
Market cap	**US$31m**

Net cash ($m) estimated at 30 June 2017, including offering	33.5
Shares in issue	7.5m
Free float	63.6%
Code	TNXP
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(13.5)	(28.4)	(82.4)
Rel (local)	(15.1)	(30.6)	(84.8)

52-week high/low	US$29.0	US$3.6

Business description

Tonix Pharmaceuticals is an emerging specialty pharmaceutical company focused on psychiatric and neurological disorders. It is developing TNX-102 SL, which is in Phase III for the treatment of post-traumatic stress disorder.

Next event

HONOR interim analysis	H118

Analysts

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

healthcare@edisongroup.com

Edison profile page

HONOR study up and running

Tonix commenced enrolment of the Phase III HONOR study on TNX-102 SL in patients with military-related PTSD in Q117. It will have up to 550 patients with a CAPS-5 of ≥33 upon entry, who will receive either 5.6mg of TNX-102 SL or placebo. The CAPS-5 is a clinician administered PTSD scale consisting of a 30-item structured interview that corresponds to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for diagnosing PTSD. According to the DSM-5, to be diagnosed with PTSD sufferers have to exhibit symptoms across four categories: intrusions, avoidance, mood and cognition, and arousal (see Exhibit 1). We expect the interim analysis in H118 with full data from 550 patients in H218 (if the study is not stopped for efficacy at the interim).

Exhibit 1: Diagnostic criteria for PTSD

Intrusions (1+ symptoms present)	Avoidance (1+ symptoms present)	Mood & cognition (2+ symptoms present)	Arousal (2+ symptoms present)
Recurring nightmares, flashbacks	Avoid people, places, things	Alterations in cognition (negative)	Exaggerated startle response
Intrusive memories (images)	Avoid thoughts/conversations	Alterations in mood (negative)	"On guard" all the time
Physiological and psychological reactions to reminders		Loss of interest	Irritability or angry outbursts
		Social withdrawal	Difficulty sleeping, concentrating

Source: DSM-5

Valuation

We have adjusted our valuation from $236m or $31.57 per basic share to $235m or $31.46 per basic share. The change in valuation is mostly due to a lower cash balance, mitigated slightly by lower R&D spending assumptions for the PTSD program.

Exhibit 2: Tonix valuation table

Product	Main Indication	Status	Prob. of success (%)	Launch year	Peak sales ($m)	Patent protection	Royalty (%)	rNPV ($)
TNX-102 SL	PTSD	Phase III	50%	2020	803	2034	25.0%	$202
Total								$202
Cash and cash equivalents (Q217e) ($m)								$33.5
Total firm value ($m)								$235
Total basic shares (10 May 2017, m)								7.49
Value per basic share ($)								$31.46
Dilutive warrants								0.7
Weighted average exercise price ($)								$11.19
Cash on exercise ($m)								$8.21
Total firm value ($m)								$244
Total number of shares (m)								8.2
Diluted value per share ($)								$29.65

Source: Edison Investment Research

Financials

Tonix reported a net loss (including non-cash expenditures) of $5.1m in Q117, down from $14.0m in Q116, mainly due to the reduction of R&D expenses from $10.7m to $3.0m. SG&A expenses also fell from $3.3m to $2.1m in Q117. We continue to expect spending to start to accelerate in Q217 though from a much lower level than before. Also, according to Note 8 in its Q117 10-Q, the company only has $6.1m in commitments for future work related to the HONOR study, indicating that the upcoming expenses for the Phase III trial may be relatively modest for a 550-patient trial

(though there were other expenses related to the HONOR study which were previously paid). As such, we have reduced our full year 2017 R&D expense estimates to $16.2m from $22.9m. The company ended Q117 with $22.4m in cash, cash equivalents and marketable securities, but has raised $16.3m in common stock offerings since the end of the quarter. We expect a funding requirement of $85m before profitability in 2023, down from $110m previously, due to the significant control of expenses. Tonix appears to be fully funded into H218.

Exhibit 3: Financial summary

	2015	2016	2017e	2018e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS				
Revenue	0	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	0	0	0	0
EBITDA	(48,162)	(38,969)	(24,682)	(26,980)
Operating Profit (before GW and except.)	(48,162)	(38,969)	(24,682)	(26,980)
Intangible Amortisation	0	0	0	(9)
Other	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(48,162)	(38,969)	(24,682)	(26,989)
Net Interest	108	127	110	105
Other	0	0	0	0
Profit Before Tax (norm)	(48,054)	(38,842)	(24,573)	(26,875)
Profit Before Tax (FRS 3)	(48,054)	(38,842)	(24,573)	(26,884)
Tax	0	0	0	0
Deferred tax	0	(0)	(0)	(0)
Profit After Tax (norm)	(48,054)	(38,842)	(24,573)	(26,875)
Profit After Tax (FRS 3)	(48,054)	(38,842)	(24,573)	(26,884)
Average Number of Shares Outstanding (m)	1.7	2.5	6.7	6.9
EPS - normalised (c)	(28.62)	(15.41)	(3.68)	(3.87)
EPS - FRS 3 ($)	(28.62)	(15.41)	(3.68)	(3.87)
Dividend per share (c)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	527	281	191	168
Intangible Assets	120	120	120	111
Tangible Assets	350	150	60	46
Other	57	11	11	11
Current Assets	43,016	26,121	20,976	16,383
Stocks	0	0	0	0
Debtors	0	0	0	0
Cash	43,016	26,121	20,976	16,383
Other	0	0	0	0
Current Liabilities	(3,049)	(872)	(841)	(841)
Creditors	(3,049)	(872)	(841)	(841)
Short term borrowings	0	0	0	0
Long Term Liabilities	(106)	(33)	(29)	(20,029)
Long term borrowings	0	0	0	(20,000)
Other long term liabilities	(106)	(33)	(29)	(29)
Net Assets	40,388	25,497	20,297	(4,319)
CASH FLOW				
Operating Cash Flow	(42,528)	(37,315)	(22,530)	(24,593)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(238)	(66)	0	0
Acquisitions/disposals	0	0	0	0
Financing	47,685	20,498	17,402	0
Dividends	0	0	0	0
Other	(11)	133	0	0
Net Cash Flow	4,908	(16,750)	(5,128)	(24,593)
Opening net debt/(cash)	(38,184)	(43,016)	(26,121)	(20,976)
HP finance leases initiated	0	0	0	0
Exchange rate movements	(4)	11	11	0
Other	-72	-156	-28	0
Closing net debt/(cash)	(43,016)	(26,121)	(20,976)	3,617

Source: Edison Investment Research

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
245 Park Avenue, 39th Floor
10167, New York
US

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