EDISON

Tonix Pharmaceuticals

Development update

HONOR study up and running

Pharma & biotech

Tonix Pharmaceuticals has commenced enrolment for the Phase III HONOR study of TNX-102 SL in military-related post-traumatic stress disorder (PTSD). It 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 is "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* ($)	DPS ($)	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	(33.5)	(4.41)	0.0	N/A	N/A
12/18e	0.0	(36.7)	(4.65)	0.0	N/A	N/A

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

Readout expected in 2018

The HONOR study has begun enrolling patients and there will be an interim analysis encompassing 275 patients (50% of the 550 total expected) after which the trial may be stopped 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.

Only one Phase III might be necessary

The company has reported that during the Initial Cross-Disciplinary Breakthrough meeting with the FDA, the agency had indicated that if HONOR study data is "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.

2019 FDA approval possible

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: $236m or $31.57 per basic share

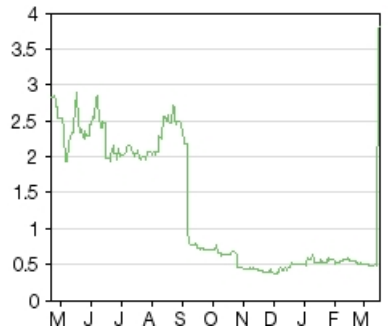
We are adjusting our valuation from $207m or $5.27 per basic share to $236m or $31.57 per basic share. The increase in valuation is due to rolling forward our NPV model and a higher cash balance. The change on a per share basis is due to dilutive equity offerings (with $17.4m in net proceeds in Q117) and a 1:10 reverse split. We expect a funding requirement of $110m before profitability in 2023, up from $80m previously, due to increasing our R&D spending assumptions in future years. However, we expect Tonix to be fully funded through the end of 2017.

20 April 2017

Price	**US$3.80**
Market cap	**US$29m**

Net cash ($m) estimated at 31 March 2017, including offering	36.8
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	(24.8)	(10.4)	(82.0)
Rel (local)	(25.7)	(15.0)	(84.6)

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 events

HONOR interim analysis	H118

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Edison profile page

HONOR study initiated

Tonix has commenced enrolment in the Phase III HONOR study on TNX-102 SL in patients with military-related PTSD. 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

Additional preclinical candidates

The company previously announced TNX-601, a novel salt of tianeptine, which the company may develop for PTSD, and TNX-801, a novel live virus vaccine for smallpox. Since then it has disclosed TNX-701, a biodefense program to protect from radiation injury. Details are limited on TNX-701 but, like TNX-801, the company believes that only animal studies may be required to establish efficacy per the FDA Animal Rule, as it would be unethical to expose humans to smallpox or radiation (however, safety and pharmacokinetic/pharmacodynamic studies would be required). Also, Tonix may be able to profit from Section 3086 of the recently enacted 21st Century Cures Act. According to that law, companies developing medical countermeasures to material threats to national security would be able to receive priority review vouchers if approved by the FDA. If used, a priority review voucher would require the FDA to aim to render a decision on a drug application within six months rather than the standard 10 months. As vouchers are transferrable, a number of them have been sold in the past, with prices ranging between $67.5m and $350m per voucher.

We are not including any of these programs in our valuation as the development path and timelines for all are unknown. We expect minimal spending on them over the course of the next 12 months but we would expect spending to accelerate quickly once they enter the clinic. We will update our model on receiving further clarity from the company

Valuation

We are adjusting our valuation from $207m or $5.27 per basic share to $236m or $31.57 per basic share. The increase in valuation is due to rolling forward our NPV model and a higher cash balance. The change on a per share basis is due to dilutive equity offerings (with $17.4m in net proceeds in Q117) and a 1:10 reverse split.

Exhibit 2: Tonix valuation table

Product	Main indication	Status	Prob. of success	Launch year	Peak sales ($m)	Patent protection	Royalty	rNPV ($m)
TNX-102 SL	PTSD	Phase III	50%	2020	803	2034	25.0%	$200
Total								$200
Cash and cash equivalents (Q117e including offering) ($m)								$36.8
Total firm value ($m)								**$236**
Total basic shares (13 April 2017, m)								7.49
Value per basic share ($)								**$31.57**
Dilutive warrants (m)								0.8
Weighted average exercise price ($)								$11.19
Cash on exercise ($m)								$8.58
Total firm value ($m)								$245
Total number of shares (m)								8.3
Diluted value per share ($)								$29.68

Source: Edison Investment Research

Financials

Tonix reported a net loss (including non-cash expenditures) of $38.8m in 2016, down from $48.1m in 2015, mainly due to the reduction of R&D expenses from $35.5m to $28.5m. Importantly, in Q416, R&D expenses were just $4.9m, down from $9.5m in Q415, as no large clinical trials were ongoing during the quarter. We expect spending to start to accelerate in Q217 due to the initiation of the HONOR study at the end of Q117. The company ended the year with $26.1m in cash and marketable securities. Subsequently, the company raised $9.1m in net proceeds over the course of February-April (however, based on the average selling price, much of it was likely done on 29 March) through an at-the-market (ATM) offering. This was the remainder of the unused portion of a $15m ATM facility previously announced in April 2016. It also raised $8.3m in net proceeds through a secondary offering that closed in April 2017. We expect a funding requirement of $110m before profitability in 2023, up from $80m previously (although we expect Tonix to be fully funded through the end of 2017). We expect the announced preclinical programs to materially add to R&D expenses in the coming years.

Exhibit 3: Financial summary

$000s	2013	2014	2015	2016	2017e	2018e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
PROFIT & LOSS						
Revenue	0	0	0	0	0	0
Cost of Sales	0	0	0	0	0	0
Gross Profit	0	0	0	0	0	0
EBITDA	(10,888)	(27,656)	(48,162)	(38,969)	(33,660)	(36,811)
Operating Profit (before GW and except.)	(10,888)	(27,656)	(48,162)	(38,969)	(33,660)	(36,811)
Intangible Amortization	0	0	0	0	(9)	(8)
Other	0	0	0	0	0	0
Exceptionals	0	0	0	0	0	0
Operating Profit	(10,888)	(27,656)	(48,162)	(38,969)	(33,669)	(36,819)
Net Interest	4	40	108	127	115	66
Other	0	0	0	0	0	0
Profit Before Tax (norm)	(10,884)	(27,616)	(48,054)	(38,842)	(33,545)	(36,744)
Profit Before Tax (FRS 3)	(10,884)	(27,616)	(48,054)	(38,842)	(33,554)	(36,753)
Tax	0	0	0	0	0	0
Deferred tax	0	(0)	0	(0)	(0)	(0)
Profit After Tax (norm)	(10,884)	(27,616)	(48,054)	(38,842)	(33,545)	(36,744)
Profit After Tax (FRS 3)	(10,884)	(27,616)	(48,054)	(38,842)	(33,554)	(36,753)
Average Number of Shares Outstanding (m)	3.2	1.0	1.7	2.5	7.6	7.9
EPS - normalized ($)	(3.37)	(27.66)	(28.62)	(15.41)	(4.41)	(4.65)
EPS - FRS 3 ($)	(3.37)	(27.66)	(28.62)	(15.41)	(4.42)	(4.65)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	45	373	527	281	266	223
Intangible Assets	0	0	120	120	111	103
Tangible Assets	45	328	350	150	144	109
Other	0	45	57	11	11	11
Current Assets	8,202	38,184	43,016	26,121	13,237	4,793
Stocks	0	0	0	0	0	0
Debtors	0	0	0	0	0	0
Cash	8,202	38,184	43,016	26,121	13,237	4,793
Other	0	0	0	0	0	0
Current Liabilities	(765)	(1,487)	(3,049)	(872)	(872)	(872)
Creditors	(765)	(1,487)	(3,049)	(872)	(872)	(872)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(13)	(68)	(106)	(33)	(33)	(25,033)
Long term borrowings	0	0	0	0	0	(25,000)
Other long term liabilities	(13)	(68)	(106)	(33)	(33)	(33)
Net Assets	7,469	37,002	40,388	25,497	12,598	(20,889)
CASH FLOW						
Operating Cash Flow	(8,517)	(22,840)	(42,528)	(37,315)	(30,243)	(33,444)
Net Interest	0	0	0	0	0	0
Tax	0	0	0	0	0	0
Capex	(15)	(319)	(238)	(66)	(30)	0
Acquisitions/disposals	0	0	0	0	0	0
Financing	10,042	47,836	47,685	20,498	17,400	0
Dividends	0	0	0	0	0	0
Other	0	0	(11)	133	0	0
Net Cash Flow	1,510	24,677	4,908	(16,750)	(12,873)	(33,444)
Opening net debt/(cash)	(1,785)	(8,202)	(38,184)	(43,016)	(26,121)	(13,237)
HP finance leases initiated	0	0	0	0	0	0
Exchange rate movements	(1)	(3)	(4)	11	11	0
Other	4908	5308	(72)	(156)	(22)	0
Closing net debt/(cash)	(8,202)	(38,184)	(43,016)	(26,121)	(13,237)	20,207

Source: Edison Investment Research, Tonix Pharmaceuticals reports

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