EDISON

Tonix Pharmaceuticals

Business update

All systems go for 2016

Pharma & biotech

With readouts from three clinical trials expected in 2016, next year will be a critical one for Tonix. First will be data from a Phase II study for TNX-201 (R-isomer of isometheptene) in Q116 for episodic tension-type headache (ETTH), which may offer an effective and non-addictive option. Next will be data from a Phase II trial for TNX-102 SL in H116 for post-traumatic stress disorder (PTSD), where current medications have spotty efficacy. Finally, the Phase III for Tonmya (TNX-102 SL) in fibromyalgia should read out in H216, which we suggest has a high chance of success.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/14	0.0	(27.6)	(2.77)	0.0	N/A	N/A
12/15e	0.0	(52.1)	(2.95)	0.0	N/A	N/A
12/16e	0.0	(45.5)	(2.31)	0.0	N/A	N/A
12/17e	2.4	(50.7)	(2.47)	0.0	N/A	N/A

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

ETTH data may open the door to partnership talks

ETTH is a highly prevalent problem with an estimated 38% of the US population suffering episodic tension-type headaches, making it a potentially attractive market for large pharma. If the TNX-201 Phase II data are positive, we would expect partnership discussions to begin in earnest in H116 and currently model a signed collaboration in 2017.

TNX-102 SL affects key symptoms of PTSD

In the Phase IIb BESTFIT trial in fibromyalgia, TNX-102 SL was shown to have a statistically significant effect on sleep, anxiety and sensitivity, which are key symptoms of PTSD sufferers. The Phase II trial is currently recruiting those with military-related PTSD, a difficult to treat group, and data are expected in H116.

We remain confident in Phase III in fibromyalgia

In the Phase IIb BESTFIT study, 34% of patients on Tonmya (TNX-102 SL) responded by at least 30% on the daily diary pain score, compared to only 20.6% for placebo (p=0.033). Importantly, the efficacy of TNX-102 SL over placebo was maintained over the course of the trial. As this is the primary endpoint in the recently launched Phase III AFFIRM trial and AFFIRM is a much larger trial (500 vs 205), we continue to assign a 70% probability of success for the program.

Valuation: $18.44 per basic share

We have decreased our valuation to $347m or $18.44 per basic share from $351m or $21.82 per basic share, mainly due to an equity offering in July that increased the share count by more than 16%. We expect the company to require further funding of around $80m until profitability, although any capital raise is not likely to occur until some, if not all, of the expected top-line data from the three ongoing trials are released, potentially minimizing dilution if the data are positive.

21 October 2015

Price	**$6.90**
Market cap	**$130m**

Estimated net cash ($m) at 30 September 2015	53.7
Shares in issue	18.8m
Free float	87.8%
Code	TNXP
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(10.0)	(20.7)	27.5
Rel (local)	(13.3)	(16.9)	19.6

52-week high/low $10.5 $5.3

Business description

Tonix is an emerging specialty pharmaceutical company focused on psychiatric and neurological disorders. It has three programs. TNX-102 SL for fibromyalgia is the most advanced of these, entering Phase III. It is also being developed for PTSD and TNX-201 is being developed for ETTH.

Next events

Three Tonmya abstracts at ACR Meeting	10 November 2015
TNX-201 ETTH data	Q116
TNX-102 SL PTSD data	H116
Tonmya FMS data	H216

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2016: A critical year

2016 will be a make-or-break year for Tonix, as we will see data from three clinical trials. First will be data from a Phase II for TNX-201, the R-isomer of isometheptene (the racemic version had been on the market in various forms for decades as a headache treatment), in Q116 for ETTH, which may offer an effective and non-addictive option for ETTH sufferers. Next will be data from a Phase II for TNX-102 SL in H116 for PTSD, where current medications have spotty efficacy, especially in military-related PTSD, a subpopulation on which Tonix's Phase II focuses. Finally, the Phase III for Tonmya (the proposed brand name for TNX-102 SL in fibromyalgia) will read out in H216, which has a high chance of success based on both prior data and clinical trial design improvements.

Exhibit 1: Tonix clinical trials

Drug	Indication	Dosage	Number of patients	Number of sites	Treatment duration	Primary endpoint	Key inclusion criteria	Expected timing
TNX-201	ETTH	140mg	200	9	Take 140mg of drug on occurrence of headache (one dose per patient)	Proportion of subjects pain free at two hours and from two to 24 hours post dose.	History of two to 14 tension-type headaches per month for the last three months.	Q116
TNX-102 SL	PTSD	2.8mg/ 5.6mg	220	24	Once daily for 12 weeks	DSM-5 symptom severity score among patients taking the 2.8mg dose.	Patients with traumas resulting in PTSD during military service, as a military contractor, in the Department of Homeland Security or law enforcement.	H116
Tonmya	Fibromyalgia	2.8mg	500	35	Once daily for 12 weeks	Proportion of subjects with a ≥30% improvement from baseline to week 12 in average pain severity score.	Fibromyalgia diagnosis and clinically stable with stable anti-depressant therapy.	H216

Source: ClinicalTrials.gov, Tonix

TNX-201 for ETTH

ETTH is a highly prevalent problem with an estimated 38% of the US population suffering episodic tension-type headaches, with approximately 25% of those suffering frequent tension-type headaches,[1] making it a potentially attractive market for large pharma. The only FDA-approved treatments include the barbiturate butalbital, with opioids and triptans used off-label, all of which can lead to addiction, tolerance and medication overuse headaches. Overall, an estimated 3.5m prescriptions are written annually for butalbital containing medications for ETTH and another 6.5m prescriptions for opioids and triptans.

TNX-201 is the R-isomer of isometheptene mucate, a headache medicine that had been on the market in various forms for decades, but without official FDA approval since 1962 due to its grandfathered drug status. The FDA began an initiative in 2006 to pull unapproved drugs off the market, and as of 2011 there are no products containing isometheptene mucate commercially available outside compounding pharmacies.

Tonix initiated a Phase II trial of 200 patients comparing 140mg of TNX-201 to placebo in June, with top-line results expected in Q116. Given the size of this indication and the expense of running a Phase III clinical trial program for ETTH, we expect the company will license this product once positive Phase II results are available, especially as large pharma should be interested in a medication that serves such a large market. Our model assumes a collaboration will be signed in 2017 with $40m upfront (the average upfront received for headache products, according to BioCentury), another $140m in milestones and a 15% royalty rate. Sales peak at $1bn, representing 25% of the butalbital + opioid + triptan market in 2033 (c 3m prescriptions). Given its apparent safety and non-habit forming qualities, this estimate appears reasonable.

1 Russell et al, European Journal of Epidemiology. 2006;21(2):153-60.

Note that we do not currently model any indications outside ETTH for TNX-201, but potential exists to use it in other pain-related indications. However, that would require a positive trial in ETTH and a large pharmaceutical partner to develop.

TNX-102 SL for PTSD

Post-traumatic stress disorder is a large but somewhat underserved market. Anyone who has had a traumatic experience (eg child abuse, rape or seeing a loved one die) can exhibit symptoms of the disease. Based on the results of a national comorbidity survey, 3.5% of the adult population have PTSD.[2]

Tonix is currently focusing on military-related PTSD, which is an unmet segment in the disorder. According to a study of sertraline in 169 veterans in an outpatient Veterans Administration Hospital setting, sertraline missed every primary and secondary efficacy measure.[3] In fact, although 89% of veterans with PTSD receive SSRIs, only 20% are considered effectively treated.[4] If TNX-102 SL is found to have efficacy in this subpopulation in Tonix's Phase II trial, there is a chance it will be able to file for approval via the Subpart H mechanism. Of course, this scenario will be very data dependent (although the exact hurdle is unclear), but it is possible given it is a relatively large trial, with 220 subjects, and the politically sensitive nature of this unmet medical need. We currently assume the company would need to run a second confirmatory trial to gain FDA approval.

Commercially, if TNX-102 SL is shown to be effective in PTSD, it should be able to have meaningful sales given the size of the population, even when adjusted for those remaining untreated and those being successfully treated by SSRI therapy. We are currently assuming $113m in sales to the military-related PTSD market and $690m to the rest ($803m in total). These estimates assume that TNX-102 SL can capture 10% of the PTSD market (c 2% of the total patient population) that is refractory to SSRIs and with a price of $6 per pill at launch. We are currently assuming that Tonix will find a strategic partner to commercialise TNX-102 SL in PTSD with a focus on those that currently fail SSRI therapy.

Tonmya for fibromyalgia

Fibromyalgia is a diffuse, chronic pain disorder where the areas of pain often fluctuate and there are a variety of comorbidities/symptoms, with-sleep related disorders (fatigue, stiffness, non-restorative sleep and difficulty falling asleep) being some of the most intense. It is a relatively common problem from which approximately 2% of Americans suffer (3.4% of women and 0.5% of men),[5] with prevalence highest among those between the ages of 55 and 64.

In May, the company launched the 500-patient Phase III AFFIRM study of Tonmya in fibromyalgia. We remain confident in the outcome of this trial despite the fact that the 205-patient Phase IIb BESTFIT trial missed the primary endpoint of mean change from baseline in the daily diary pain score during week 12. This is due to the fact that it showed a statistically significant improvement in a number of secondary endpoints, including the endpoint that has been selected as the primary endpoint for the AFFIRM trial (30% responder rate on daily diary pain score). Importantly, the efficacy was maintained through the length of the study in the treatment arm, while it trended down in the placebo arm (see Exhibit 2).

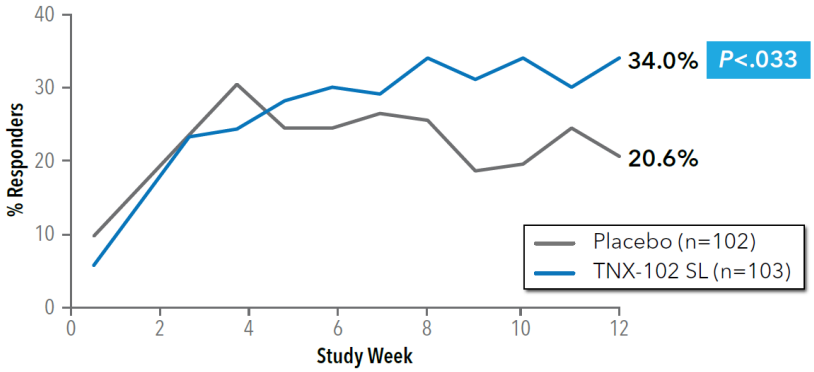
[2] Kessler et al, Arch Gen Psych 2005;62:617-627.

[3] Friedman et al, J Clin Psychiatry 2007;68(5):711-720.

[4] Pharmacotherapy for Post-traumatic Stress Disorder in Combat Veterans by Walter Alexander, P&T, January 2012.

[5] D.A. Marcus, A. Deodhar, Fibromyalgia, DOI 10.1007/978-1-4419-1609-9_2.

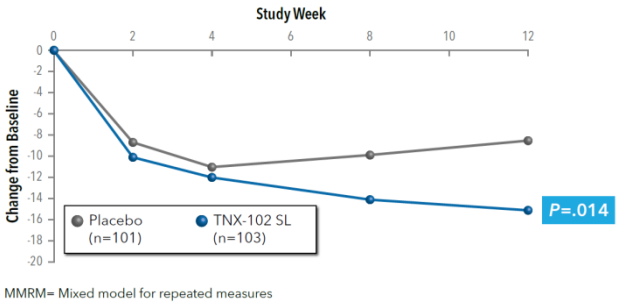
Exhibit 2: BESTFIT – 30% responder rate on daily diary pain score



Source: Tonix (EULAR 2015)

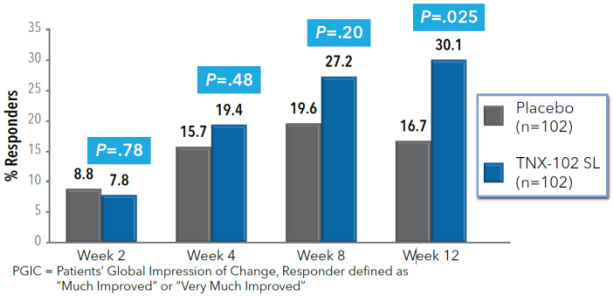
Furthermore, the total score from the revised Fibromyalgia Impact Questionnaire (FIQR), as well as the responder rate on the Patients' Global Impression of Change (PGIC) scale, was consistent with the daily diary pain scale score (see Exhibits 3 and 4).

Exhibit 3: BESTFIT – FIQR change from baseline



Source: Tonix (EULAR 2015)

Exhibit 4: BESTFIT – PGIC responder rate



Source: Tonix (EULAR 2015)

We currently model $343m in peak sales, the equivalent of c 30m doses annually (equivalent to 1-2% of the total fibromyalgia patient population). As with ETTH and PTSD, we believe Tonix will need to find a commercial partner for Tonmya. Our model assumes $50m upfront, another $80m in milestones and a 25% royalty rate (the relatively high rate is due to our belief that Tonix will only partner the product after approval to maximize its value).

Valuation

We have decreased our valuation to $347m or $18.44 per basic share from $351m or $21.82 per basic share, mainly due to a $20.1m equity offering in July that increased the share count by more than 16%. As we view the ETTH and PTSD programs as high risk and assign 20% and 30% probabilities of success to them, respectively, positive trial results would lead to us increase the value of the company, possibly by a large percentage.

Exhibit 5: Tonix valuation model

Product	Main indication	Status	Probability of success	Launch year	Peak sales ($m)	Patent protection	Royalty	rNPV
TNX-102 SL	Fibromyalgia	Phase III	70%	2019	343	2034	25.0%	$130
TNX-102 SL	PTSD	Phase II	30%	2020	803	2034	25.0%	$102
TNX-201	ETTH	Phase II	20%	2020	1,006	2033	15.0%	$62
Total								$293
Cash and cash equivalents (Q315) ($m)								53.7
Total firm value ($m)								347
Total basic shares (m)								18.8
Value per basic share ($)								18.44
Stock options (6/2015, m)								1.7
Weighted average exercise price ($)								10.54
Cash on exercise ($m)								18.2
Total firm value ($m)								365
Total number of shares (m)								20.5
Diluted value per share ($)								17.78

Source: Edison Investment Research

Financials

Tonix reported $48.7m in cash and cash equivalents at the end of Q215 and conducted an equity offering in July, which provided it with $18.7m in net proceeds. The company spent $8.9m on R&D and $2.9m on SG&A in Q215. We project that R&D spending will accelerate for the rest of the year as clinical trials progress. We have kept our estimates for future revenue and spending substantially the same, although we removed $20m in illustrative long-term debt in 2015 due to the equity offering. We expect the company to require another $80m until profitability in 2020 (we currently expect additional financing in 2016, 2017 and 2018, which we model as long-term debt), although any capital raise is not likely to occur until after some, if not all, of the expected top-line data from the three ongoing trials are released, potentially minimizing dilution if the data are positive. We have assumed that the company will partner fibromyalgia and PTSD after approval, to maximize the deal terms and ETTH after Phase II.

Exhibit 6: Financial summary

$'000s	2012	2013	2014	2015e	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	0	0	0	0	0	2,360
Cost of Sales	0	0	0	0	0	0
Gross Profit	0	0	0	0	0	2,360
EBITDA	(6,662)	(10,888)	(27,656)	(52,325)	(45,727)	(47,687)
Operating Profit (before GW and except.)	(6,662)	(10,888)	(27,656)	(52,325)	(45,727)	(47,687)
Intangible Amortisation	0	0	0	(4)	(9)	(8)
Other	0	0	0	0	0	0
Exceptionals	0	0	0	0	0	0
Operating Profit	(6,662)	(10,888)	(27,656)	(52,330)	(45,735)	(47,695)
Net Interest	(1,611)	4	40	194	186	(3,027)
Other	(1,177)	0	0	0	0	0
Profit Before Tax (norm)	(9,450)	(10,884)	(27,616)	(52,131)	(45,541)	(50,714)
Profit Before Tax (FRS 3)	(9,450)	(10,884)	(27,616)	(52,136)	(45,550)	(50,722)
Tax	0	0	0	0	0	0
Deferred tax	0	0	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(9,450)	(10,884)	(27,616)	(52,131)	(45,541)	(50,714)
Profit After Tax (FRS 3)	(9,450)	(10,884)	(27,616)	(52,136)	(45,550)	(50,722)
Average Number of Shares Outstanding (m)	1.7	3.2	10.0	17.6	19.7	20.5
EPS - normalised ($)	(5.58)	(3.37)	(2.77)	(2.95)	(2.31)	(2.47)
EPS - FRS 3 ($)	(5.58)	(3.37)	(2.77)	(2.95)	(2.31)	(2.47)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	47	45	373	504	443	395
Intangible Assets	0	0	0	116	107	99
Tangible Assets	47	45	328	343	291	251
Other	0	0	45	45	45	45
Current Assets	1,785	8,202	38,184	37,130	34,599	44,337
Stocks	0	0	0	0	0	0
Debtors	0	0	0	0	0	420
Cash	1,785	8,202	38,184	37,130	34,599	43,917
Other	0	0	0	0	0	0
Current Liabilities	(825)	(765)	(1,487)	(2,770)	(2,770)	(2,770)
Creditors	(825)	(765)	(1,487)	(2,770)	(2,770)	(2,770)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	(20)	(13)	(68)	(65)	(40,065)	(97,705)
Long term borrowings	0	0	0	0	(40,000)	(60,000)
Other long term liabilities	(20)	(13)	(68)	(65)	(65)	(37,705)
Net Assets	987	7,469	37,002	34,799	(7,793)	(55,743)
CASH FLOW						
Operating Cash Flow	(5,713)	(8,517)	(22,840)	(48,690)	(42,687)	(7,626)
Net Interest	0	0	0	158	186	(3,027)
Tax	0	0	0	0	0	0
Capex	(36)	(15)	(319)	(219)	(30)	(30)
Acquisitions/disposals	0	0	0	0	0	0
Financing	6,933	10,042	47,836	47,700	0	0
Dividends	0	0	0	0	0	0
Other	0	0	0	0	0	0
Net Cash Flow	1,184	1,510	24,677	(1,051)	(42,531)	(10,683)
Opening net debt/(cash)	(41)	(1,785)	(8,202)	(38,184)	(37,130)	5,401
HP finance leases initiated	0	0	0	0	0	0
Exchange rate movements	0	(1)	(3)	(3)	0	0
Other	560	4908	5308	0	0	0
Closing net debt/(cash)	(1,785)	(8,202)	(38,184)	(37,130)	5,401	16,083

Source: Company accounts, Edison Investment Research

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