

Tonix Pharmaceuticals

Business update

All systems go for 2016

Pharma & biotech

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

Analysts

Maxim Jacobs	+1 646 653 7027
Christian Glennie	+44 (0)20 3077 5727

healthcare@edisongroup.com

[Edison profile page](#)

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.

Tonix Pharmaceuticals is a research client of Edison Investment Research Limited

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 $\geq 30\%$ 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).

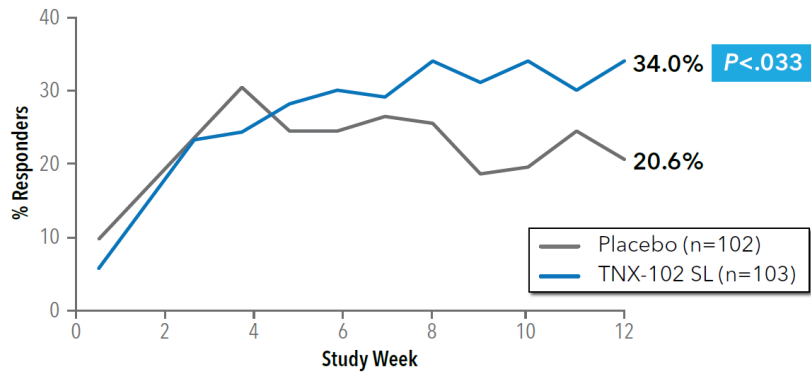
² Kessler et al, Arch Gen Psych 2005;62:617-627.

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.

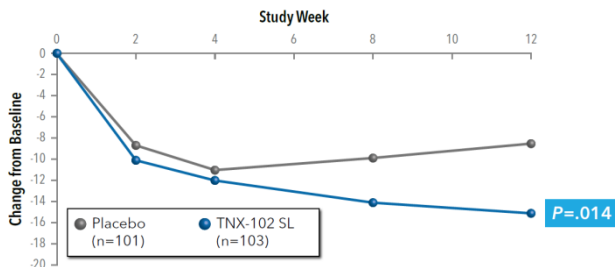
Exhibit 2: BESTFIT – 30% responder rate on daily diary pain score



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).

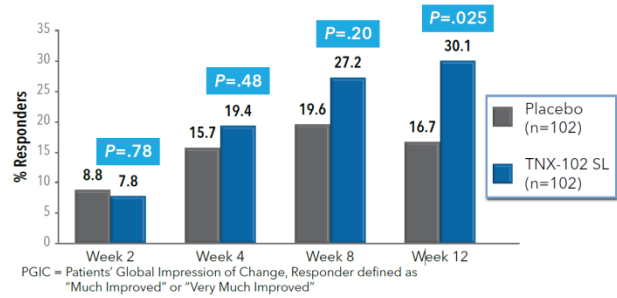
Exhibit 3: BESTFIT – FIQR change from baseline



MMRM= Mixed model for repeated measures

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

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Frankfurt, Sydney and Wellington. Edison is authorised and regulated by the Financial Conduct Authority (www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

DISCLAIMER

Copyright 2015 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Tonix Pharmaceuticals and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2015. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.