Zacks Small-Cap Research

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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Developing New Smallpox Vaccine…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL PTSD, TNXP is valued at $2/share. This model is highly dependent upon continued clinical success of TNX-102 SL in PTSD and will be adjusted accordingly based upon future clinical results.

Current Price (03/08/17)	$0.51
Valuation	**$2.00**

OUTLOOK

On March 2, 2017, Tonix Pharmaceuticals Holding Corp. (TNXP) announced the successful synthesis of a smallpox-preventing vaccine (TNX-801), which is a live form of a horsepox virus shown to have protective activity in mice. The current smallpox vaccine, Sanofi's ACAM 2000, is not administered to first responders due to the potential safety concerns not outweighing the benefits. Tonix believes that TNX-801 may offer a safer vaccine that could be utilized to vaccinate first responders and the general population in the case of a viral outbreak. In addition, the 21st Century Cares Act provides for a priority review voucher for drugs or vaccines intended to treat threats that present a national security threat. Sarepta (SRPT) recently sold a priority review voucher to Gilead (GILD) for $125 million.

SUMMARY DATA

52-Week High	**$2.90**
52-Week Low	**$0.37**
One-Year Return (%)	**-78.75**
Beta	**2.84**
Average Daily Volume (sh)	**917,469**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**10**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 A	0 E	0 E
2017					0 E
2018					0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.71 A	-$0.73 A	-$0.72 A	-$0.71 A	-$2.86 A
2016	-$0.74 A	-$0.50 A	-$0.29 A	-$0.19 E	-$1.52 E
2017					-$0.56 E
2018					-$0.57 E

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WHAT'S NEW

TNX-801: An Improved SmallPox Vaccine

On March 2, 2017, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the company had successfully synthesized a vaccine that potentially protects against smallpox. The vaccine candidate (TNX-801) is a live form of the horsepox virus and has already demonstrated protective activity in mice. The company is hopeful that the newly synthesized vaccine will be safer to use than the currently available vaccine (Sanofi's ACAM2000), which is not utilized as a prophylactic vaccine due to safety concerns not outweighing the potential benefit, however it is kept as a national stockpile in the event of a viral outbreak.

Smallpox

The term smallpox refers to an infectious disease, now eradicated, that was caused by one of two virus variants, *Variola major* and *Variola minor*. Infection resulted in the development of a maculopapular rash along with raised, fluid-filled blisters. Mortality rates differed depending on which strain of the virus was contracted; those infected with *V. major* had a morality rate of 15-45% while those infected with *V. minor* had a 1-5% mortality rate (Behbehani, 1983).

Following a vigorous worldwide vaccination program, the World Health Organization (WHO) declared smallpox eradicated in 1979. However, there are two "official" smallpox stocks kept in storage; one at the Center's for Disease Control (CDC) in Atlanta, Georgia and the other at Russia's State Research Center of Virology and Biotechnology VECTOR. Some have speculated that large amounts of weaponized smallpox "disappeared" in the breakup of the former Soviet Union, which could have been transferred to rogue nations. While the U.S. civilian population is not vaccinated, U.S. troops that are prepared to deploy to the Korean peninsula continue to be vaccinated as a precautionary measure. Lastly, in 2014, several vials of smallpox were found at the Food and Drug Administration (FDA) while cleaning out an old storage room. The samples were sent to the CDC for testing before being destroyed.

Smallpox Vaccine

The vaccines utilized in the eradication of smallpox were composed of live vaccinia virus cultured on the skin of animals, typically cows. A number of different vaccinia virus strains were used in the vaccines by the end of the vaccination campaign, typically named after the country or City in which they were propagated (e.g., New York City Board of Health, Copenhagen, IOS [Brazil], Tsien tsien [China], etc.). These vaccines were not subject to clonal purification and represented "swarms" of many different clones. The methods used to propagate them likely selected for faster growing viruses. After almost 200 years of divergent evolution, they were analyzed by genomic sequencing and found to share common origins with either horsepox or a virus similar to it. The traditional vaccines also contained a number of contaminants (e.g., bacteria, hair, parts of insects, etc.) that would not be suitable for a modern-day vaccine. Further, propagation on cows presented the risk of bovine spongiform encephalopathy, or 'Mad Cow Disease'.

These issues led to the development of ACAM2000, a licensed smallpox vaccine comprised of a cloned vaccinia virus cultured on Vero cells. The FDA approved ACAM2000 in August 2007, however it is not an ideal vaccine based on a relatively high incidence of serious adverse events, including the fact that 1 in 175 healthy adults who received the vaccine for the first time developed myocarditis (FDA). Even with these risks, ACAM2000 is in the national stockpile of emergency medical supplies. In April 2008, Acambis (later acquired by Sanofi for $550 million) won a 10-year, $425 million contract from the CDC to supply at least nine million doses of ACAM2000 per year beginning in 2010. ACAM2000 has a shelf life of 72 months, thus a portion of the stockpile must be continually replaced each year. Thus far, Sanofi has supplied more than 200 million doses of ACAM2000 to the national stockpile.

TNX-801

TNX-801 is a synthetic, live form of the horsepox virus developed using techniques broadly applicable to the field of 'synthetic biology'. Tonix did not supply many details regarding the new horsepox virus vaccine that has been constructed and the research has not yet been submitted for peer review in a scientific publication. The reason for this is that the company believes an open discussion may be necessary regarding the implications of publishing

methods for synthesizing poxviruses, for example the work may have implications regarding the preservation of the smallpox virus stocks.

TNX-801 was constructed by Professor David Evans, Ph.D. and research associate Ryan Noyce, Ph.D. at the University of Alberta. Tonix wholly owns the synthesized horsepox virus stock and related sequences and the company has initiated manufacturing activities for additional preclinical testing. In order to gain approval, Tonix would need to show safety in a healthy adult population along with efficacy in two animal models, one of which would be non-human primates. Those studies would likely not initiate until 2018.

Priority Review Voucher

In addition to potentially selling TNX-801 to the U.S. government to be included in the national stockpile, approval of TNX-801 could include the issuance of a priority review voucher, which allows the holder of the voucher to receive an expedited six-month review from the FDA for a new drug application (NDA) or biologics license application (BLA) instead of the usual ten-month review. The 21st Century Cures Act created a priority review voucher for medical countermeasures, which are drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat. A vaccine to protect against smallpox would almost certainly fall into that category. Priority review vouchers are also awarded for the development of treatments for certain tropical diseases and rare pediatric diseases.

Priority review vouchers are fully transferrable, and a number of companies that have been issued the vouchers in the past have sold them. The following table shows how many priority review vouchers have been issued along with the current status of the voucher, if known.

Priority Review Vouchers

Voucher Award Date	Voucher Type	Voucher Awardee	Voucher Status
2009	Tropical Disease	Novartis	Used for BLA for canakinumab
2012	Tropical Disease	Janssen	Not used
2014	Rare Pediatric Disease	BioMarin	Sold to Sanofi for $67.5M on July 30, 2014
2014	Tropical Disease	Knight Therapeutics	Sold to Gilead for $125M on Nov. 19, 2014
2015	Rare Pediatric Disease	United Therapeutics	Sold to AbbVie for $350M on Aug. 19, 2015
2015	Rare Pediatric Disease	Asklepion Pharmaceuticals	Transferred to Retrophin and sold to Sanofi for $245M on May 27, 2015
2015	Rare Pediatric Disease	Wellstat Therapeutics	Transferred to AstraZeneca
2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Not used
2016	Tropical Disease	PaxVax Bermuda	Not used
2016	Rare Pediatric Disease	Sarepta Therapeutics	Sold to Gilead for $125M on Feb. 21, 2017
2016	Rare Pediatric Disease	Ionis Pharmaceuticals	Not used
2017	Rare Pediatric Disease	Marathon Pharmaceuticals	Not used

*Note: Gilead purchased a priority review voucher during the second quarter of 2016, but who it was purchased from and for how much was not disclosed

Source: raps.org / Zacks SCR

Of note, five priority review vouchers have been sold with the most expensive being $350 million that AbbVie paid United Therapeutics in August 2015. Since that time the price for a priority review voucher seems to have fallen, with Gilead paying $125 million for one in February 2017. However, were Tonix able to secure a priority review voucher for TNX-801 and sell it for even half of what Gilead paid in February 2017 it would be a significant source of non-dilutive capital.

Synthetic Biology

Tonix is the first group to synthesize a poxvirus. Prior to this, □X174, polio, and influenza had all been synthesized, however horsepox is much larger and more complex than those viruses. Recombinant poxviruses have been used as vaccines against infectious diseases and cancer, representing potential opportunities for the use of the horsepox virus. The current HIV vaccine trial in South Africa is based on a canarypox virus that expresses HIV proteins. In addition, anti-cancer virus vaccines are in development by a number of companies. Jennerex, which is developing genetically engineered oncolytic vaccina viruses that specifically target and kill tumor cells, was acquired by SillaJen in November 2013 for approximately $150 million. Amgen's Imlygic® (talimogene laherparepvec), a genetically engineered herpes virus, was the first oncolytic virus to be approved by the FDA in October 2015. Imlygic® was developed by BioVex, which was acquired by Amgen in January 2011 for up to $1 billion (including a $425 million upfront payment). The ability to construct a poxvirus suggests that vaccines for both infectious disease and oncology might be developed using synthetic horsepox or other poxviruses. However, we are uncertain from the

public information what aspects of the disclosed technology Tonix owns beyond the statement that Tonix owns the horsepox vaccine for smallpox.

Conclusion

We are intrigued by Tonix's development of a new smallpox vaccine and look forward to learning more about it when the company releases additional details. If Tonix were to get the vaccine approved it could offer two potential sources of revenue: the ability to sell the vaccine for use in the national stockpile as well as the ability to sell the priority review voucher, which we believe would be awarded as TNX-801 should be considered a medical countermeasure under the definition in the 21st Century Cures Act. While priority review vouchers may never again command the $350 million that AbbVie paid in 2015, we would not be surprised to see their price remain in the $75-$100 million range. We are not including TNX-801 in our model as of now, however if the company continues to develop the vaccine and initiate testing for regulatory submission there is the potential for upside to our valuation, which currently stands at $2.00 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals Holding Corp.
Income Statement

Tonix Pharmaceuticals	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
TNX-102 SL (PTSD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Research & Collaborations	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$35.5	$10.7	$7.5	$5.5	$5.0	$28.7	$17.0	$20.0
SG&A	$12.7	$3.3	$2.3	$2.1	$2.2	$10.0	$8.0	$8.5
Operating Income	($48.2)	($14.0)	($9.8)	($7.6)	($7.2)	($38.7)	($25.0)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($48.1)	($14.0)	($9.8)	($7.6)	($7.2)	($38.7)	($25.0)	($28.5)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($48.1)	($14.0)	($9.8)	($7.6)	($7.2)	($38.7)	($25.0)	($28.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.86)**	**($0.74)**	**($0.50)**	**($0.29)**	**($0.19)**	**($1.52)**	**($0.56)**	**($0.57)**
YOY Growth	*3.5%*	-	-	-	-	*-46.9%*	*-63.5%*	*2.6%*
Weighted Shares Outstanding	16.8	18.9	19.7	26.1	37.0	25.4	45.0	50.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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