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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Developing COVID-19 Skin Test to Examine T Cell Immunity…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia, TNX-1800, and TNX-1300, TNXP is valued at $3.75/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (03/09/21)	$1.02
Valuation	**$3.75**

OUTLOOK

On February 8, 2021, Tonix Pharmaceuticals Holding Corp. (TNXP) announced a plan to develop a diagnostic skin test, TNX-2100, to measure the delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2. The test is designed to measure the T cell immunity to SARS-CoV-2, which unlike antibody detection can't be done with a simple, standardized laboratory test. TNX-2100 could potentially serve as a biomarker for T cell immunity, a method to stratify participants in COVID-19 vaccine trials, an endpoint in COVID-19 vaccine trials, and a biomarker of vaccine durability. We anticipate an IND being filed in the second quarter of 2021 with a clinical trial likely to start in the second half of 2021.

SUMMARY DATA

52-Week High	**$2.00**
52-Week Low	**$0.53**
One-Year Return (%)	**3.02**
Beta	**1.33**
Average Daily Volume (sh)	**36,685,140**
Shares Outstanding (mil)	**324**
Market Capitalization ($mil)	**$330**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**0**
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 2018 Estimate	**-3.0**
P/E using 2019 Estimate	**-3.2**

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

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$12.90 A	-$9.50 A	-$5.69 A	-$2.86 A	-$19.33 A
2020	-$0.37 A	-$0.23 A	-$0.09 A	-$0.08 E	-$0.50 E
2021					-$0.21 E
2022					-$0.17 E

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WHAT'S NEW

Business Update

On February 8, 2021, Tonix Pharmaceutical Holdings Corp. (TNXP) announced a plan to develop a diagnostic skin test, TNX-2100, as a means to test for a delayed-type hypersensitivity (DTH) reaction to SARS-CoV2, the virus that causes COVID-19, following receipt of the written response from a Pre-IND meeting with the FDA.

The test is modeled after the Tuberculosis (TB) skin test (Tubersol®, Aplisol®, or the generic Mantoux test) that can determine if an individual has been exposed to the bacteria that causes tuberculosis, *Mycobacterium tuberculosis*. The TB skin test is performed by injecting a small amount (0.1 mL) of tuberculin units (purified protein derivative) intradermally on the flexor surface of the forearm halfway between the elbow and wrist using a 26- or 27-gauge needle. A small, pale, raised area on the skin is seen immediately following the test (lower left image) and the result of the test is read approximately 48-72 hours after administration. If a person has been exposed to TB, a DTH immune response will occur and result in generalized local inflammation (lower right image). The area of skin induration, or palpable raised hardened area, is measured in millimeters across the forearm as the reported result.



Source: Shutterstock.com



Source: Shutterstock.com

TNX-2100 is a test that is comprised of three different mixtures (TNX-2110, -2120, -2130) of synthetic peptides that correspond to different proteins of SARS-CoV-2. TNX-2110 represents multiple proteins from SARS-CoV-2, TNX-2120 represents only the spike protein of SARS-CoV-2, and TNX-2130 is representative of several proteins but not the spike protein. All three tests will be administered during the same procedure by application to three separate areas on the forearm in a similar manner to the TB skin test. They are designed for multiple potential applications: 1) As a biomarker for cellular immunity and protective immunity to SARS-CoV-2; 2) a method for stratifying participants in a COVID-19 vaccine trial by immune status; 3) an endpoint in COVID-19 vaccine trials; and 4) a biomarker of durability of vaccine protection.

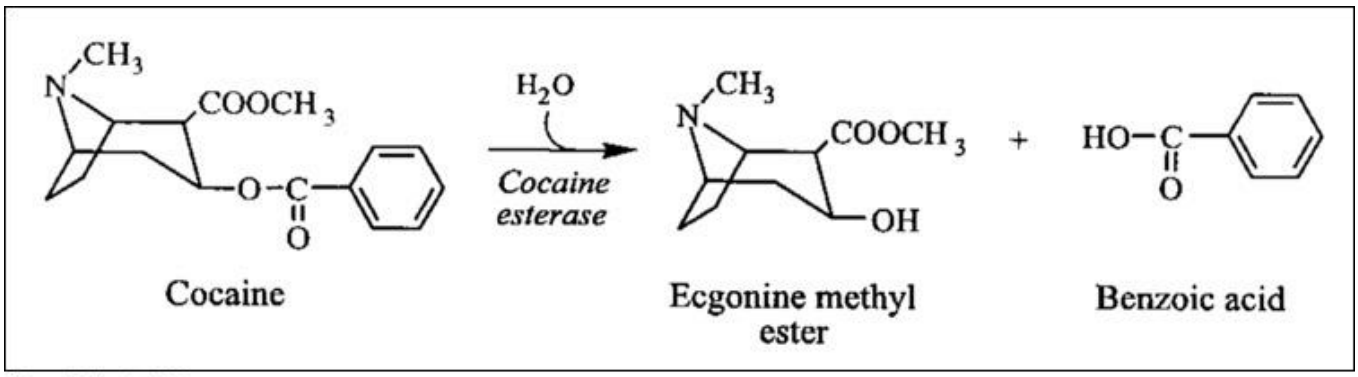
As an example, if an individual is positive against all three peptide mixtures it is expected that they would have had prior exposure to SARS-CoV-2. If an individual was successfully vaccinated using one of the currently available vaccines against SARS-CoV-2 and had not been previously exposed or infected then they likely would only be positive to TNX-2120. Clinical trials are anticipated to correlate the skin test results with prior clinical history in order to determine the sensitivity and specificity of TNX-2100 as a marker for T cell immunity in individuals both pre- and post-immunization with the current COVID-19 vaccines, individuals who have recovered from COVID-19, and those with active SARS-CoV-2 infections.

We anticipate the company submitting an IND for TNX-2100 in the second quarter of 2021 as Tonix has already manufactured cGMP batches of peptides. This would allow clinical trials to initiate in the second half of 2021.

TNX-1300 Update

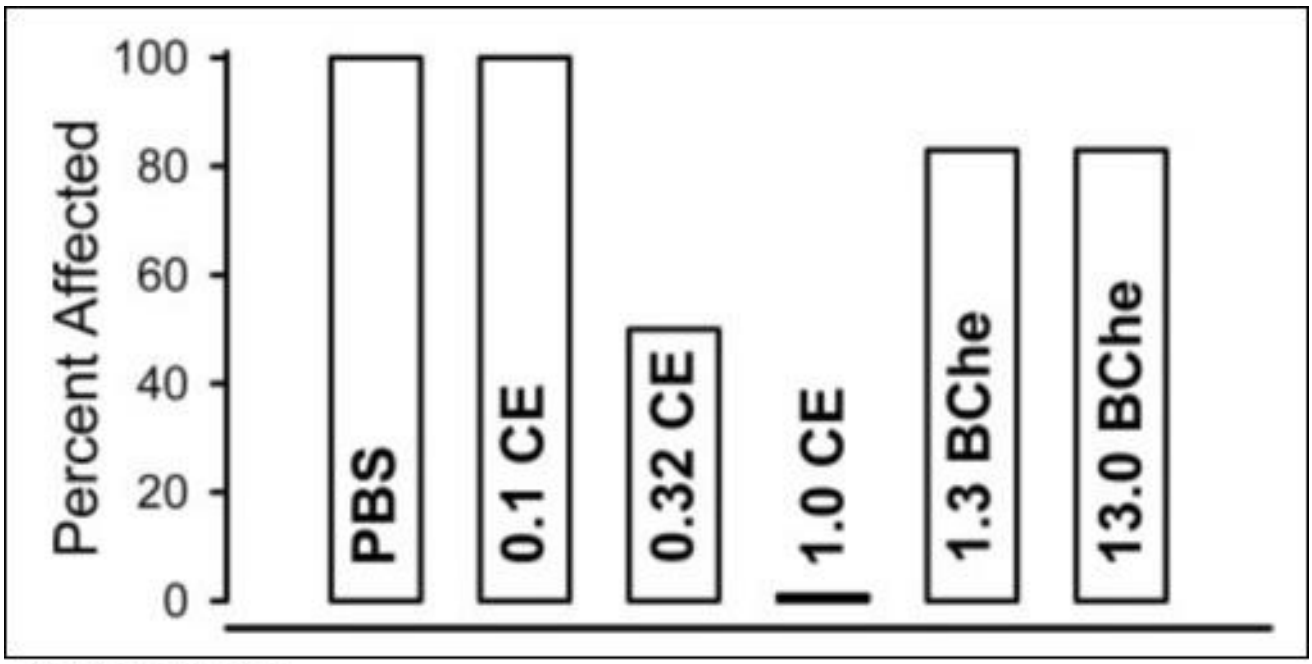
We anticipate Tonix initiating a Phase 2 clinical trial of TNX-1300, a double mutant cocaine esterase, for the treatment of cocaine intoxication before the end of the second quarter of 2021. Tonix licensed the asset in May 2019 from Columbia University, which has breakthrough therapy designation from the U.S. FDA.

TNX-1300 is a recombinant enzyme derived from the *cocE* gene of a *Rhodococcus* species that utilizes cocaine as a sole source of carbon and nitrogen (Bresler *et al*., 2000). The degradation of cocaine by the enzyme is shown in the following figure.



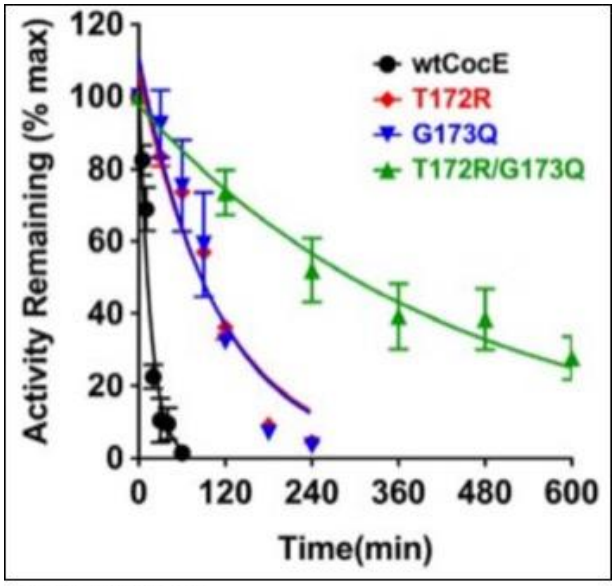
Source: Bresler *et al*., 2000

The CocE enzyme was tested in a rat model of cocaine toxicity to determine if it could protect the animals from cocaine-induced lethality (Cooper *et al*., 2006). The following chart shows that administration of increasing concentrations of CocE (CE) 1 minute before a lethal 180 mg/kg IP dose of cocaine results in increasing protection from cocaine-induced lethality (shown as "percent affected"). In fact, it required a 1000 mg/kg dose of cocaine to overcome the protective effects of 1 mg CocE (LD_{50} for IP dose is 70 mg/kg cocaine). BChe (butyrylcholinesterase) is an endogenous human esterase that also degrades cocaine into benzoic acid and ecgonine methyl ester, however its catalytic efficiency is much lower than CocE (Xie *et al*., 1999), and as shown in the following figure it is not nearly as efficient at protecting animals from a lethal dose of cocaine.



Source: Cooper *et al*., 2006

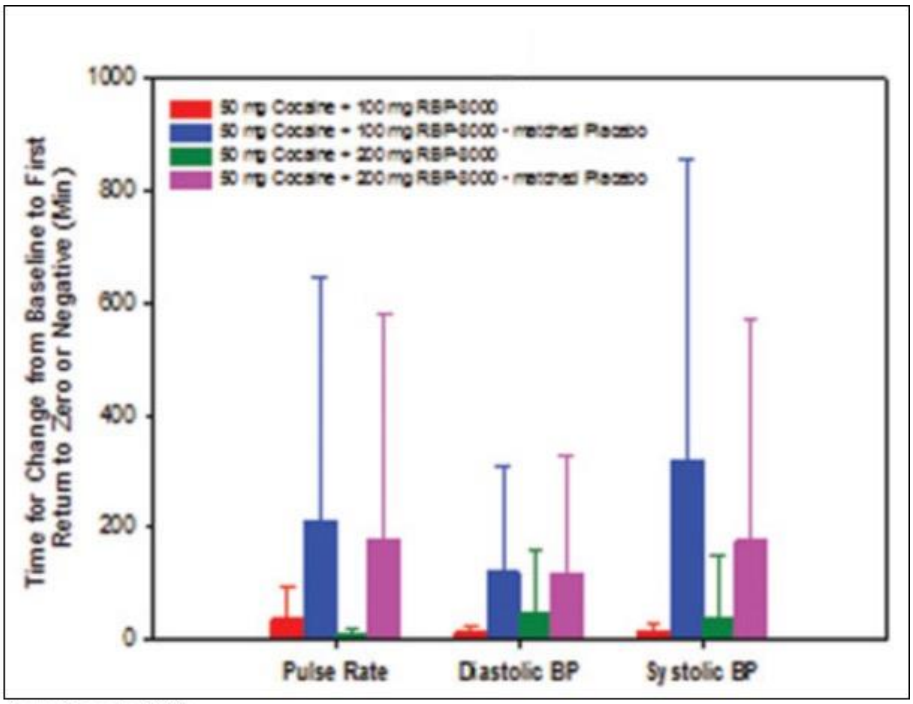
One of the issues with the native CocE enzyme is that its half-life is only a few minutes at physiological temperature (37ºC) (Cooper *et al*., 2006). Thus, a study was performed to develop thermostable variants of CocE using a computational approach along with *in vitro* and *in vivo* studies (Gao *et al*., 2009). A variant was identified with two amino acid substitutions (T172R/G173Q) that resulted in increased stability at 37ºC. The following figure shows that the double mutant CocE enzyme retains more of its activity at 37ºC for a longer period of time compared to the wild-type enzyme or the enzymes with one or the other mutations.



Source: Gao *et al.*, 2009

The double mutant CocE enzyme (then called RBP-8000, now TNX-1300) was evaluated in a Phase 2 clinical trial conducted by Reckitt Benckiser Pharmaceuticals, the previous licensee to the product (NCT01846481). It was a double blind, placebo controlled, randomized, four-sequence, two-period cross-over study. Subjects were non-treatment seekers with a DSM-IV diagnosis of cocaine abuse. During the study period, subjects were given an IV infusion of 50 mg of cocaine over 10 minutes followed by TNX-1300 (100 mg or 200 mg) or matching placebo one minute after completion of the cocaine infusion. Outcomes included pharmacokinetics of both cocaine and TNX-1300 along with any effect by TNX-1300 on cocaine-induced physiological changes (Nasser *et al.*, 2014).

A total of 29 subjects were randomized in the trial. Safety results showed that no anti-TNX-1300 antibodies were detected in any of the subjects at any time point. In addition, there were no clinically significant abnormalities in vital signs, clinical laboratory markers, or physical examinations. A total of seven subjects reported treatment-emergent adverse events that were considered related to treatment with any study drug, with most being assessed as mild in severity. Of note, vital signs of subjects treated with TNX-1300 returned to or below baseline earlier than subjects that received placebo, as shown in the following figure.



Source: Nasser *et al.*, 2014

Plasma cocaine rapidly decreased following administration of TNX-1300, with a 90% drop of peak plasma cocaine concentrations within two minutes and a 95% decline in plasma cocaine exposure. The 200 mg dose of TNX-1300 produced a longer-lasting effect on cocaine pharmacokinetics compared to the 100 mg dose. These preliminary results fully support the continued develop of TNX-1300 as a treatment for cocaine intoxication.

Financial Update

In the past few months, Tonix strengthened its balance sheet through multiple financing transactions. On January 13, 2021, Tonix raised gross proceeds of approximately $40M from the sale of 50 million shares of common stock at $0.80 per share. On February 9, 2021, Tonix raised gross proceeds of approximately $70M from the sale of approximately 58 million shares at a price of $1.20 per share. In addition, the shares outstanding increased by approximately 75 million from the end of the third quarter 2020 through the beginning of January before the $40 million financing as we believe the company was utilizing its ATM. At an average price per share during that period of $0.65, we estimate Tonix raised approximately $50 million. Thus, we estimate that Tonix currently has approximately $190 million after accounting for fourth quarter cash burn and fees/expenses associated with each of the capital raises. As of February 9, 2020, Tonix had approximately 323.9 million shares outstanding.

Conclusion

The SARS-CoV-2 skin test being developed by Tonix could represent a cost-effective means to learn more about the cellular immune response to the virus. Seroprevalence studies of anti-SARS-CoV-2 antibodies continue to show a relatively low level of circulating antibodies in the general population, all while COVID-19 cases are continuing to drop. Thus, there could be a relatively large percentage of the population that has cellular immunity against SARS-CoV-2, and TNX-2100 could provide valuable information regarding population-level immunity to the virus. In addition, TNX-2100 could be a valuable tool in determining cellular immune responses to the various COVID-19 vaccines being developed along with information pertaining to duration of immunity.

In the immediate future, we anticipate non-human primate efficacy data for TNX-1800 (Covid-19 vaccine) along with the initiation of a Phase 2 open-label study of TNX-1300 for cocaine intoxication before the end of the second quarter of 2021. We have updated our model following the recent financings and the additions to the pipeline, and our current valuation is $3.75 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0.0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$18.2	$4.7	$10.6	$8.8	$11.0	$35.1	$60.0	$70.0
SG&A	$10.6	$2.6	$3.6	$3.2	$3.0	$12.4	$13.0	$15.0
Operating Income	($28.8)	($7.3)	($14.2)	($12.0)	($14.0)	($47.5)	($73.0)	($85.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.0	$0.0	$0.0	$0.1	$0.1	$0.4	$0.4
Pre-Tax Income	($28.6)	($7.3)	($14.2)	($12.0)	($13.9)	($47.3)	($72.6)	($84.6)
Preferred Stock Deemed Dividend	$2.5	$1.26	$0.0	$0.0	$0.0	$1.3	$0.0	$0.0
Warrant Deemed Dividend	$0.0	$0.45	$0.0	$0.0	$0.0	$0.5	$0.0	$0.0
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($31.1)	($9.0)	($14.2)	($12.0)	($13.9)	($49.1)	($72.6)	($84.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($19.33)**	**($0.37)**	**($0.23)**	**($0.09)**	**($0.08)**	**($0.50)**	**($0.21)**	**($0.17)**
YOY Growth	*-92.8%*	-	-	-	-	*-97.4%*	*-58.9%*	*-18.4%*
Weighted Shares Outstanding	1.6	24.0	62.4	127.2	175.0	97.2	350.0	500.0

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

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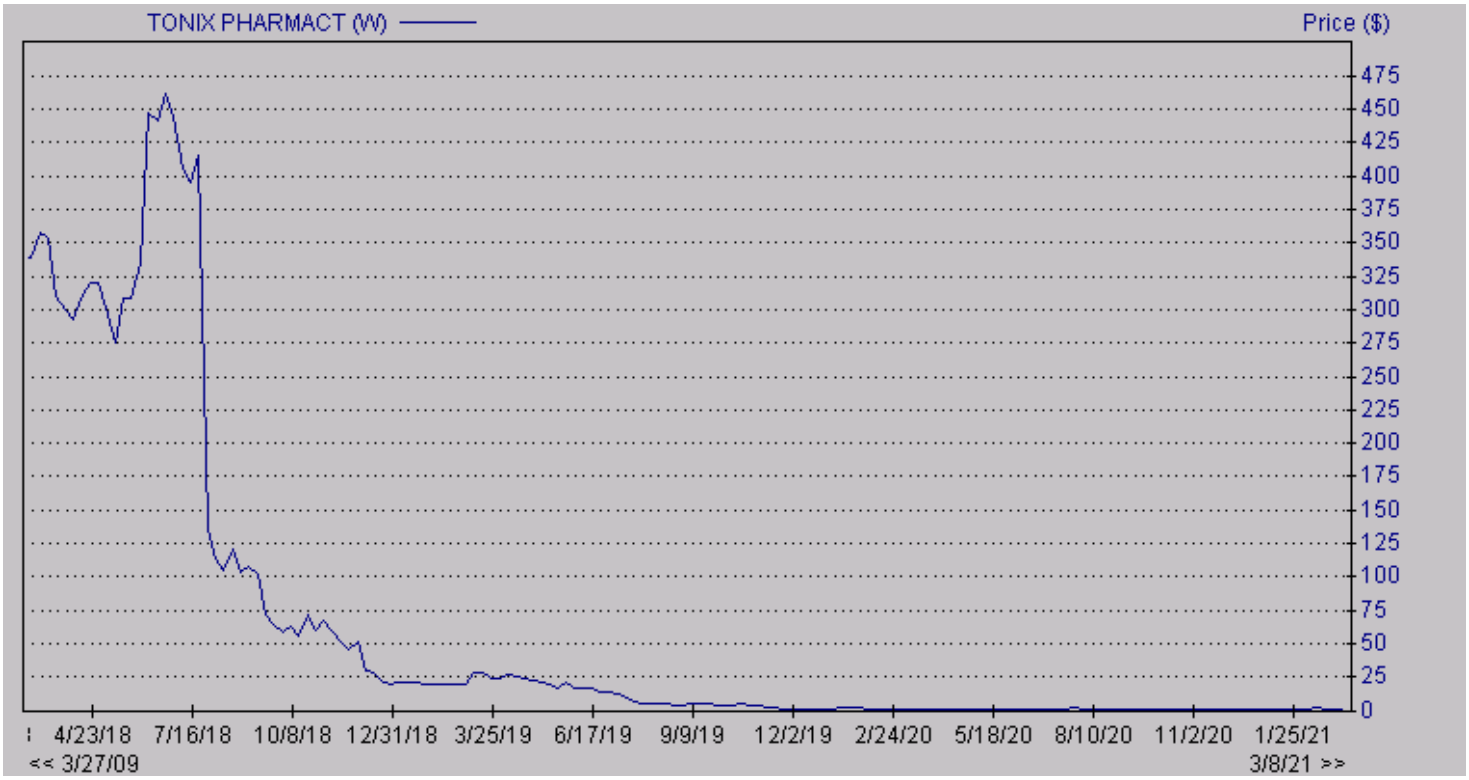
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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