"It's the oddest thing: every time I've done something that was intended to make money, I lost money."

- RJ Kirk, Chairman and CEO of XON

## **EXECUTIVE SUMMARY**

## Part 1: Zika virus hype is nonsensical

XON shares have rallied ~100% over the past 3 months due to hype around the company's ability to use genetically-modified mosquitoes to combat Zika virus. XON's technology has recently been questioned by high ranking officials from the WHO, CDC and NIH. XON's technology won't work, is way too expensive, and is many years from generating even miniscule revenue from Zika virus despite adding \$2 billion of market cap due to the hype. **We wonder why XON's longtime COO just left¹ in advance of such a "great" opportunity?** 

Smart money is hitting the "eject" button and leaving retail investors holding the bag. In addition to the abrupt resignation of RJ Kirk's right hand man Krishnan mentioned above, Third Point, a well-known hedge fund and an investor since 2011, recently sold their entire position. The head of the UltraVector division resigned after just 9 months on the job. The head of the Consumer Sector resigned after just 6 months. Moreover, all of the "smart money" healthcare-focused investment funds such as Brown Brothers, Orbimed and Healthcore have stayed far, far away from owning XON shares.

#### Part 2: Revenues overstated by 50% through transactions with related parties

XON, together with CEO RJ Kirk's private investment firm Third Security, have created an intricate web of microcap, zero revenue, free cash flow negative companies that seem to exist solely for the purpose of inflating XON's revenue and profitability. XON and Third Security inject cash into these shell companies who, in exchange, "buy" services from XON with that cash. The cash in from XON/Third Security rarely exceeds the cash that comes back meaning that XON is effectively turning these financing cash flows back into revenue and profits through round-tripping their own cash.

**Partners are almost exclusively failed and/or shady microcaps.** Since it seems that very few "real" companies will partner with XON in their apparent scheme to create fake revenues, XON is forced to partner with failed/failing and/or shady microcaps that have no other options. Purported "blue chip" partners like Sanofi and Eli Lilly/Elanco have never even mentioned Intrexon in their public disclosures.

**Mismatch between XON reported revenue recognition from partners and amounts partners claim to have paid to XON.** Even the related party transactions that create XON's revenue might be overstated. We compared XON financial statements with customer financial statements and found large discrepancies between the revenue that XON reports and the payments that customers claim to have made to XON.

## Part 3: Biofuels are a pipe dream

Many companies have failed at biofuels over the past decade and we believe XON is no different. In fact, the head of the division at XON has worked at three failed biofuel startups in a row. Isobutanol prices have collapsed. Also, XON claims they have constructed a pilot plant that we think is nothing like a real pilot plant.

1

<sup>&</sup>lt;sup>1</sup> http://investors.dna.com/2016-03-21-Intrexon-Realigns-Responsibilities-Augments-Team

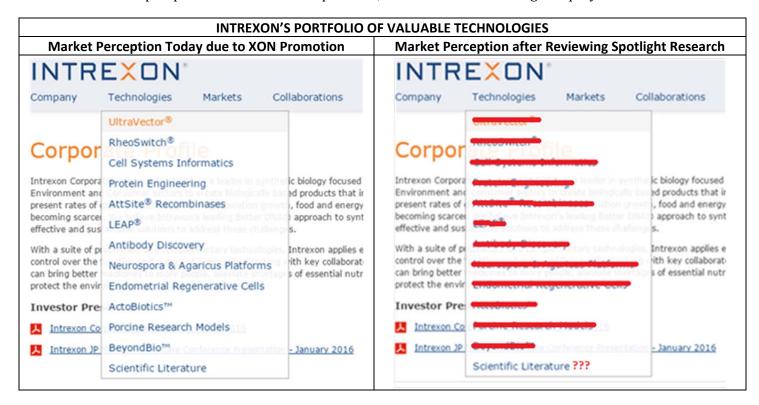
## Part 4: Only non-related party business sells cattle

Trans Ova Technologies was acquired less than 1.5 years ago for 1.8x revenue, yet XON trades at 20x revenue. Up until late 2014, XON's only business was the transactions through related parties discussed above. In late 2014, XON acquired Trans Ova, a company that sells pregnant cows and cow embryos. It does not use XON technology. This company was acquired for just \$128 million and now represents 50% of revenues at XON, a  $\sim$ \$4.5 BILLION company.

# Parts 5-8: Self-proclaimed "Google of life sciences" technology platform is an overhyped, undifferentiated collection of commodity and failed products

XON employs lots of fancy jargon to explain their core technologies. We examined each closely and we found nothing more than a collection of products that anyone can (and does) use themselves smashed together with failed science experiments from years ago. One of XON's key technologies was literally given away by its previous owner.

A staple of the XON stock market promotion is that given the portfolio model approach, if one or two technologies or products fail, XON can re-direct investor attention to the latest hot technology or product. Currently the attention is focused on Oxitec and Zika. ~50% of sellside questions on the 4Q15 earnings call were related to Oxitec, and RJ Kirk is happy to entertain them, devoting half of the Q&A call time to this single subsidiary. In Parts 5 through 8 of our report, we will leave Intrexon no place to hide as we thoroughly investigate each of Intrexon's 12 core technologies. Without valuable technologies, there can be no credible prospects for commercialization for the myriad early stage opportunities that XON is pursuing via Exclusive Channel Collaborations and Joint-Ventures. Thus, while XON can pursue as many clinical trails utilizing their commoditized technology as they like to keep the dream alive, such trails in our view are extremely unlikely to result in valuable commercial products in the future. And without a real prospect of commercialized products, there can be no meaningful equity value for XON.



### **Conclusion**

<u>We believe that XON is the Theranos<sup>2</sup> of the public markets</u>. After the dust had settled on Theranos, Bill Maris, founder of Google Ventures, explained to Business Insider why Google Ventures did not invest in Theranos while it had been investing in other hot biotech startups like 23andMe and Flatiron Health:

"We looked at it a couple times, but there was so much hand-waving — like, Look over here! — that we couldn't figure it out," Maris tells Business Insider. "So, we just had someone from our life-science investment team go into Walgreens and take the test. And it wasn't that difficult for anyone to determine that things may not be what they seem here."<sup>3</sup>

Similar to Maris, we saw the "hand-waving" at Intrexon and the promotional activity of the company's charismatic founder as serious red flags and began our intensive due diligence. We our shocked by what we have found. Through this 110 page, 21,000+ word investigative report that will be released as a mini-series, we believe that we will systematically debunk all core aspects of the bull case to comprehensively demonstrate that things are definitively not "what they seem here."

	<u>Theranos</u>	<u>Intrexon</u>		
Founder-driven company	Yes	Yes		
Founder considered to be a "genius" by supporters	Yes	Yes		
Founder's actual background not in same field as company	Yes – student	Yes – lawyer		
Peak valuation	\$9 billion	~\$8.5 billion		
Wildly bullish claims made by management and investors	Yes	Yes		
"Smart money" healthcare investors stayed away	Yes	Yes		
Proprietary technology is an amazing "secret"	Yes	Yes		
Proprietary technology not commercialized	Yes	Yes		
Proprietary technology actually represents tiny part of revenues	Yes	Yes		
Actual business based on using commodity technologies	Yes	Yes		
	THE WALL STREET JOURNAL.  15 tests on Edison	Revenue from Proprietary Tech excl. Collaboration		
Contribution to results from proprietary technology <sup>4</sup>	190 tests on traditional lab machines  Sources: the company (total number of tests); former employee (subtotals)	Collaboration Revenue  Trans Ova Revenue  Source: Intrexon 2015 10-K		

<sup>&</sup>lt;sup>2</sup> http://medcitynews.com/2016/02/theranos-doomsday-clock-full-timeline-rise-fall/?rf=1

<sup>&</sup>lt;sup>3</sup> http://www.businessinsider.com/bill-maris-explains-why-gv-didnt-invest-in-theranos-2015-10

<sup>4</sup> http://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901

Intrexon has been around for more than 17 years and commercialized effectively <u>zero</u> meaningful commercial products using their own technology. Their technology is a "secret." Nobody can explain exactly what they do. Not their employees, not sell-side analysts and not the people who own the stock. The company is only able to generate revenue through related party transactions and selling livestock. The fair value of this company is miniscule compared to its current market cap of ~\$4.5 billion.

#### **PART 1: ZIKA VIRUS HYPE IS NONSENSICAL**

Since bottoming at slightly over \$18 per share in mid-January, XON stock is up  $\sim 100\%$ . The main reason for this strong performance is a retail-investor-driven bubble based on hype around the recent outbreak of Zika virus. These investors hope that an XON subsidiary called Oxitec that makes genetically-modified (GM) mosquitoes can help combat the outbreak by reducing mosquito populations in affected and at-risk areas.

There are many reasons that this hype is unwarranted.

Reason #1: XON has added more than \$2 billion of market cap for an asset they bought for \$160 million 6 months ago

XON acquired Oxitec for \$160 million in August of 2015. The technology was already well understood. The potential was already well understood. And, in an open market transaction, Oxitec management and shareholders determined that the value of the company was \$160 million - 93% less than the value the market is currently ascribing to it.

XON Share Price before Zika	\$18.52
XON share price today	\$37.00
Market Cap before Zika	2,156
Market Cap today	<u>4,307</u>
Change in Market Cap (value of Zika hype)	2,151
Oxitec purchase price	160
Hype/reality price	<b>13.4</b> x

Reason #2: Oxitec has been around for more than a decade and has generated practically no revenues ever

Oxitec was founded in 2002 in the United Kingdom. We believe that <u>over the following 13 years, the company has</u> failed to generate any meaningful amount of revenue.

The evidence is pretty clear that, at acquisition, Oxitec was a tiny company. Footnotes in SEC documents filed by XON show that Oxitec had only \$125,000 of trade receivables, \$1.2 million of PP&E and just \$120,000 of deferred revenue. In fact, almost the entire purchase price was allocated to intangible assets and goodwill.

CI	¢.	2.700
Cash	\$	3,780
Trade receivables		125
Other receivables		7,395
Prepaid expenses and other		121
Property, plant, and equipment		1,198
Intangible assets		96,854
Total assets acquired		109,473
Accounts payable		1,187
Accrued compensation and benefits		246
Other accrued liabilities		210
Deferred revenue		120
Deferred tax liabilities		12,584
Total liabilities assumed		14,347
Net assets acquired		95.126
Goodwill		51,268
Total consideration	\$	146,394

Even today, Oxitec's LinkedIn profile shows just 54 total employees

(<a href="https://www.linkedin.com/vsearch/p?f">https://www.linkedin.com/vsearch/p?f</a> CC=1357474&trk=rr\_connectedness) and the company profile says it has "11-50 employees"



Source: LinkedIn

An obvious pushback to the above analyses would be that Zika virus is a game-changer. We think that it clearly is not. The main deployments of Oxitec's mosquitoes had been to treat Dengue fever, a disease that is much more prevalent and much more dangerous than Zika. Oxitec had also previously targeted malaria before apparently giving up on that. Dengue and malaria affect many more people and are far more dangerous than Zika is alleged to be. If Oxitec wasn't able to generate any meaningful amount of revenues over more than decade fighting dengue and malaria, we ask the question: why should Zika be any different?

				Zika	VS.
	<u>Dengue</u>	<u>Malaria</u>	<u>Zika</u>	<u>Dengue</u>	<u>Malaria</u>
Cases per year	75,000,000	198,000,000	1,500,000	-98%	-100%
Deaths per year	22,000	500,000	0	-100%	-100%
Deaths + birth defects	22,000	500,000	4,000	-82%	-100%

Source: CDC, press reports

But never let the facts get in the way of a good story, particularly when it involves scaring consumers/retail investors into buying up Intrexon stock.

As Randall Kirk explained on CNBC:

"I'm sure many of your viewers are getting sick of hearing about Zika... but the truth is buckle up. It's going to get much, much worse."



A question from the CNBC anchor later in the interview:

"So we were just mentioning that everyone is getting tired of hearing about Zika although it is a huge problem obviously and that does seem to be something that's really giving a lot of attention to Intrexon lately, but is that the right thing for investors to be focusing on for you guys, at least in terms of near term revenue driver?

And the response from Kirk began with: ""I think it actually will be a near term revenue driver."

Reason #3: Oxitec's mosquitoes might not actually work

There is evidence to suggest that Oxitec's mosquitoes actually make things worse rather than better.

A village in Brazil where the mosquitoes were being tested showed an *increase* in dengue fever cases.

# GM mosquitoes increase spread of dengue fever in Brazilian town, causing state of emergency to be renewed

Friday, August 29, 2014 by: Jonathan Benson, staff writer

http://www.naturalnews.com/046656 GM mosquitoes dengue fever Brazil.html

Increased dengue fever prevalence was also cited by Malaysia as they abandoned trials for the mosquitoes in favor of a vaccine

# Malacca won't release GMO mosquitoes

http://www.therakyatpost.com/news/2014/07/14/malacca-wont-release-gmo-mosquitoes/

Oxitec has never actually measured the impact of dengue fever on its GM mosquito releases in any country, despite a scientific consensus that such measurements would be necessary to determine whether the technology was effective. In fact, Oxitec and its research partners have admitted that the experiments being conducted would not be adequate to assess the impacts on the disease.

to assess the efficacy of new technologies.<sup>5,6</sup> Oxitec and its research partners in Brazil have both admitted that the experiments there (the largest ones conducted) are inadequate to assess the impacts on disease.<sup>7,8</sup> In February 2014, a dengue emergency was declared in Jacobina, Brazil, one of the areas where Oxitec conducted its experiments.<sup>9</sup>

Source: GeneWatch

http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Oxitec GWbrief Mar15.pdf

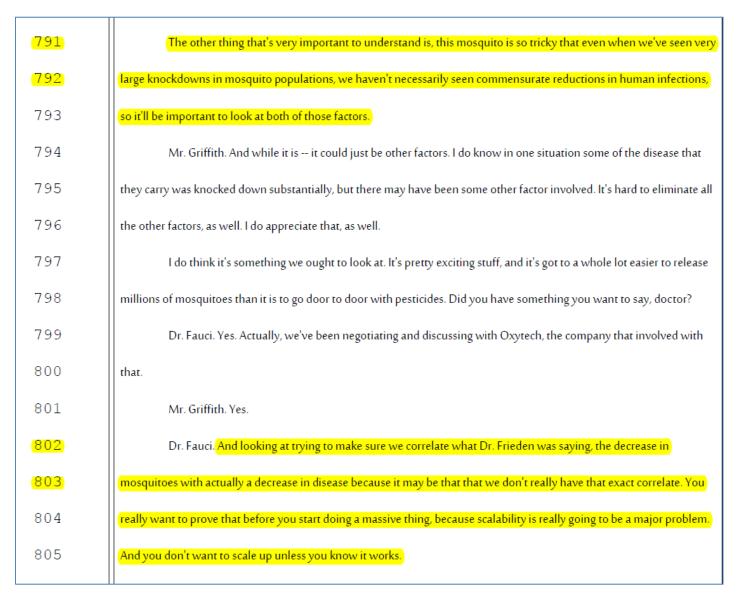
Reason #4: High-ranking US CDC and NIH officials have expressed concerns about Oxitec's GM mosquitoes

At a March 2015 hearing<sup>5</sup>, Dr. Thomas Frieden (Director of CDC) and Dr. Anthony Fauci (Director National Institute of Allergy and Infectious Diseases, NIH) questioned the practicality of Oxitec mosquitoes and highlighted the lack of correlation between mosquito population reduction and disease transmission reduction<sup>6</sup>. Both individuals indicated that a decline in infections (something Oxitec has never demonstrated and never even tried to scientifically prove) would be necessary to roll-out Oxitec on a larger scale.

784	Dr. Fauci and Dr. Frieden, you all have been involved somewhat in this with the genetically engineered
785	mosquito. How is your agency assisting the company that's developed this novel technology? It looks like it's trials of
786	5,000 people, lots of mosquitoes. Looks like it's been about 90 percent effective in some of the areas it's been tried in.
787	Dr. Frieden. We have a number of vector control experts who have consulted with the company and others,
(788)	listened to them as well as provided our input. I think one of the challenges is the issue of scalability. These particular
(789)	mosquitoes don't fly very far, so you may have to release millions upon millions of them every short distance in order to
790	get the knockdown.

6 http://docs.house.gov/meetings/IF/IF02/20160302/104594/HHRG-114-IF02-Transcript-20160302.pdf (lines 784-804)

<sup>&</sup>lt;sup>5</sup> https://energycommerce.house.gov/hearings-and-votes/hearings/examining-us-public-health-response-zika-virus



Source: House.gov

Reason #5: The World Health Organization explicitly does NOT recommend using Oxitec's mosquitoes to combat Zika

On March 18, the World Health Organization (WHO) Vector Control Advisory Group (VCAG) released its recommendations for controlling Zika virus. The organization recommended targeted residual spraying, space spraying, larvae control and personal protection measures to reduce the transmission of Zika. For Oxitec's OX513A mosquito, the WHO explicitly said that deployment was "not currently recommended" and that current technologies are "effective."

Well implemented vector control programmes using existing tools and strategies are effective in reducing the transmission of Aedes-borne diseases, including Zika virus. These tools should be promoted and used to control the Zika virus. They include: (i) targeted residual spraying; (ii) space spraying; (iii) larval control; and (iv) personal protection measures.

Full-scale programmatic deployment is not currently recommended for any of the five new potential tools reviewed by VCAG.

The WHO instead said that Oxitec's technology should be one of a few options that are studied for potential future use and said that "more evidence is required." Specific to Oxitec, they said that there was an "absence of epidemiological data."

...the VCAG recommended the carefully planned pilot deployment under operational conditions of two tools (Wolbachia-based biocontrol and OX513A transgenic mosquitoes) accompanied by rigorous independent monitoring and evaluation.

The VCAG concluded that more evidence is required before consideration of the pilot deployment of the three additional tools reviewed (sterile insect technique, vector traps and attractive toxic sugar baits)."<sup>7</sup>

We would further note that OX513A from Oxitec is only option 2b. Option 2a is Wolbachia-based biocontrol (see below).

## Specific recommendations

2a. Microbial control of human pathogens in adult vectors (Wolbachia).
 Available evidence indicates that symbiotic Wolbachia spp. bacteria, when introduced into Ae. aegypti populations, reduce the mosquitoes' ability to transmit arboviruses to humans. Laboratory results show that Wolbachia infection reduces viral replication of dengue, chikungunya and Zika viruses within Aedes mosquitoes, and eliminates or substantially delays appearance of virus in mosquito saliva – reducing its competence for transmitting dengue viruses. The strategy involves establishing and sustaining Wolbachia in local Aedes spp. mosquito populations, thereby providing ongoing protection from virus transmission.

## VCAG recommendation

This committee recommends carefully planned pilot deployment under operational conditions accompanied by rigorous independent monitoring and evaluation that builds entomological capacity to support operational use. Plans for randomised control trials (RCTs) with epidemiological outcomes should continue to build evidence for routine programmatic use of *Wolbachia* against *Aedes*-borne diseases.

2b. Mosquito population reduction through genetic manipulation. OX513A is

Source: WHO

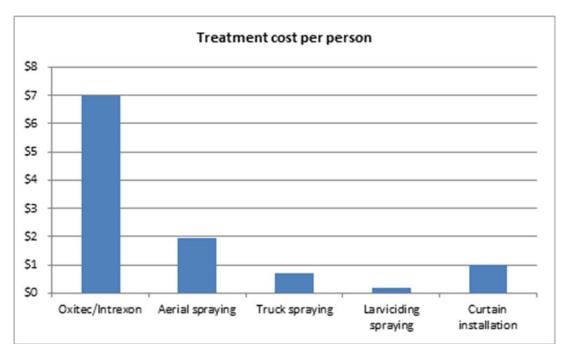
The costs associated with WHO's recommendations (targeted residual spraying, space spraying, larvae control and personal protection measures) are all less than \$2 per person. We estimate that aerial spraying has a cost of less than \$2/person. Manatee County Florida was able to conduct 3 separate aerial sprays at a total cost of \$600,0008. With a population of over 300,0009 the cost of aerial spraying is well below \$2 per person per spray. Manatee County also estimated total ground-released larvicides and adulticides at \$225,000, putting the per

<sup>&</sup>lt;sup>7</sup> http://www.who.int/neglected diseases/news/mosquito vector control response/en/

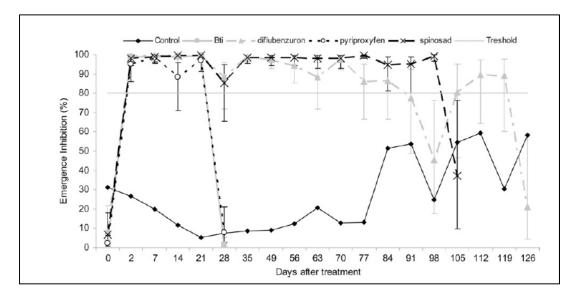
http://www.mamca.org/2013meeting/0314 1100 lesser.pdf (slide 31 for aerial, truck-based spraying slide 27)

https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=Manatee+County+population

person cost below \$1. Larviciding campaigns are estimated to have an average cost of \$0.20 per person<sup>10</sup>. Even installing curtains treated with insecticide is roughly \$2/household (less than \$1/person)<sup>11</sup>



A study titled "Field Efficacy of New Larvicide Products for Control of Multi-Resistant Aedes aegypti Populations in Martinique (French West Indies)" shows the reduction in A. aegypti following various types of larvicide techniques. Each technique showed a significant decrease in mosquito population (see below). 12



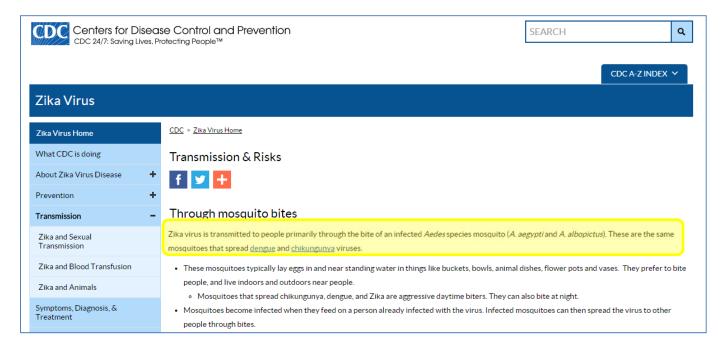
Reason #6: Even if Oxitec's mosquitoes worked, they only work on one of the three mosquito types that carry Zika, so they wouldn't prevent infection

<sup>&</sup>lt;sup>10</sup> http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3156.2007.01889.x/epdf

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3083742/

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3005507/

There are two mosquito carriers of Zika in the western hemisphere and both are in Brazil – Oxitec's products only deal with one type. According to the Centers for Disease Control and Prevention (CDC), in the Western Hemisphere, Zika virus is carried by <u>both</u> Aedes aegypti and Aedes albopictus<sup>13</sup>. In Western Africa, the Aedes africanus mosquito is also a carrier of Zika.



While A. aegypti is typically thought to be the most prominent Aedes in the Western hemisphere, a Brazilian journal article titled "Zika virus in Brazil and the danger of infestation by Aedes (Stegomyia) mosquitos" describes the strong presence of A. albopictus in Brazil as well:

<sup>&</sup>lt;sup>13</sup> http://www.cdc.gov/zika/transmission/

<sup>&</sup>quot;Zika virus in Brazil and the danger of infestation by Aedes (Stegomyia) mosquitos" http://www.scielo.br/scielo.php?script=sci\_arttext&pid=S0037-86822015005003102

## Excerpt from "Zika virus in Brazil and the danger of infestation by Aedes (Stegomyia) mosquitos"

Marcondes CB and Ximenes MFFM - Zika virus and Aedes (Stegomyia) mosquitoes

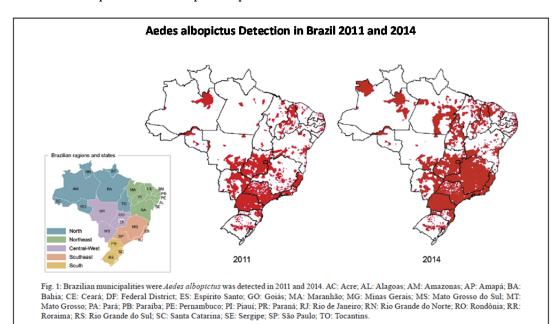
Aedes albopictus was previously distributed only in Asia, but was transported to other continents via commerce, and it is now considered an important invasive mosquito<sup>(57)</sup>. In Brazil, Ae. albopictus was present in 59% of municipalities in 2014<sup>(58)</sup> and in 24 of 27 states<sup>(59)</sup>. It is adapted to both urban and sylvatic habitats, including bromeliads<sup>(60)</sup>, tree holes (also with Ae. aegypti and Ae. vittatus)<sup>(61)</sup>, and perforated bamboo intermodes<sup>(62)</sup>, and is a suspected link for YFV between preserved and modified environments in the south and southeast regions of Brazil<sup>(63)</sup>. This species is both endophagic and exophagic, feeding on a wide range of hosts, in comparison to Ae. aegypti that feeds mostly indoors on humans.

Experimentally, Aedes albopictus may transmit 22 different arboviruses (64). As a good experimental vector of YFV (65), Ae. albopictus could potentially transmit YFV if an overlap

of ZIKV in Southeast Asia and Oceania<sup>(43)</sup>. The finding of *Wyeomyia mitchellii*, a sylvatic bromeliad-associated American species, in Hawaii<sup>(75)</sup> and French Polynesia<sup>(76)</sup> indicates the possibility of invasion of new regions by mosquitoes not associated to human modified habitats.

Aedes koreicus and Aedes japonicus are 2 examples of invaders of potential health importance. Well adapted to rock pools and other containers (77)(78)(79)(80), the former species is now widely distributed in Europe (77), and the latter is distributed in the USA and Europe (78)(79)(80). The ecological and health implications of 5 invaders of Europe (Aedes aegypti, Aedes albopictus, Aedes japonicus, Aedes koreicus and Aedes atropalpus) were thoroughly reviewed, with the first 2 species already involved in disease transmission in Europe and Aedes albopictus and Aedes japonicus already showing widespread distribution (80).

## Below is a map of Aedes albopictus' presence in Brazil<sup>15</sup>



It gets worse for XON and Oxitec. In labs, researchers demonstrated that it was possible to infect Brazil's most common mosquito, Culex quinquefaciatus, with Zika. <sup>16</sup> Culex quinquefaciatus is 20x more common than A. aegypti in Brazil.

<sup>&</sup>lt;sup>15</sup> "Updating the geographical distribution and frequency of Aedes albopitcus in Brazil with remarks regarding its range in the Americas" http://www.bioline.org.br/pdf?oc14116

There is a high likelihood that one unintended consequence of reducing A. aegypti mosquito populations would be that it would actually increase the populations of other Zika-carrying mosquitoes. Indeed, the scientific literature suggests that, if you reduce one mosquito population in an area, the other species in the area will likely displace it.

According to a study performed in India, in areas with both mosquitos, as one population decreases, the other grows. <sup>17</sup>

Bull. Org. mond. Santé
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1967, 37

1967, 37, 437-446

## Observations on Possible Competitive Displacement between Populations of *Aedes aegypti* Linnaeus and *Aedes albopictus* Skuse in Calcutta\*

SUSHIL K. GILOTRA,1 LLOYD E. ROZEBOOM 2 & N. C. BHATTACHARYA 3

The possibility of competitive displacement in Calcutta between Aedes aegypti, a known vector of arboviruses, and A. albopictus, a suspected vector, was explored by general collections of immature stages from all types of breeding-places and by exposing oviposition traps in tenement houses, and gardens in urban, suburban, and rural environments. A. aegypti was predominant in houses and tenements in urban areas, but A. albopictus was not excluded. Both species occurred in about equal densities in small urban gardens. In suburban and rural areas, A. albopictus was predominant, or the only one of the two species present. It readily entered houses for the purpose of oviposition, especially in the absence of A. aegypti.

It is suggested that the two species are exhibiting the effect of competitive displacement, with A. aegypti being favoured in urban premises and A. albopictus in the outdoor environment of suburban and rural areas, while in small urban gardens there is a state of equilibrium in which the densities of the two populations are about equal. The possibility cannot be excluded that eradication of A. aegypti in the city might lead to an increase in the A. albopictus population in houses and tenement dwellings.

GeneWatch also cites these risks in the troubling outbreak of dengue fever in a town in Brazil where Oxitec was conducting some of its experiments:

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<sup>&</sup>lt;sup>16</sup> http://www.reuters.com/article/us-health-zika-brazil-idUSKCN0W52AW

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2554274/

assess the impacts on disease.<sup>7,8</sup> In February 2014, a dengue emergency was declared in Jacobina, Brazil, one of the areas where Oxitec conducted its experiments.<sup>9</sup>

There are a number of mechanisms through which releasing GM mosquitoes could make the impacts of the dengue virus worse, including:

- (i) In areas of high mosquito abundance, where dengue is endemic, reducing the frequency of biting can increase the incidence of the more serious form and often fatal of the disease, dengue haemorrhagic fever (DHF), by reducing cross-immunity to the four different serotypes of the dengue virus, or increasing the incidence of dengue fever (DF) due to age-related effects (known as 'endemic stability'). 10,11
- (ii) Enabling an increase or expansion in territory occupied by the competitor species Aedes albopictus, an important vector for dengue and chikungunya in many countries which may be harder to eradicate than Aedes aegypti. 12,13,14 Brazilian experts have warned that dengue may mutate so that Aedes albopictus becomes a more important dengue vector in such circumstances. 15 The potentially devastating effect of a single mutation in the virus has already been observed with chikungunya. 16 Aedes albopictus has been responsible for concurrent epidemics of dengue and chikungunya in some countries and its presence can also extend the dengue season and perhaps introduce new viruses. 17,18,19,20,21,22

Source: GeneWatch

## Reason #7: There are other, better, cheaper ways to target Zika-carrying mosquitoes... and Brazil agrees

While GM mosquitoes certainly sound "sexy," they are far from the most effective, practical solution for combating mosquito-borne illness, and they are far-and-away the most expensive and uneconomic.

In fact, the Brazilian government (the same government that is "testing" Oxitec's mosquitoes) appears to have chosen to go a different route by recently announcing that they would release sterilized male mosquitoes and NOT Oxitec's GM mosquitoes.

The math is clear: sterilized mosquitoes cost just \$400/1 million mosquitoes <sup>18</sup> and have the same effect as Oxitec's mosquitoes (unviable offspring). Given the economics and efficacy, it is no surprise that this method appears to have emerged as the leading choice of treatment by the Brazilian government. If the irradiated mosquitoes are released in the same proportion as Oxitec's mosquitoes, roughly 5,000 mosquitoes are needed per person.<sup>19</sup> This equates to a per person cost of roughly \$2.

<sup>18</sup> http://www.telegraph.co.uk/news/worldnews/zika/12169491/Brazil-plans-to-zap-mosquitoes-with-radiation-to-halt-spread-of-Zika-virus.html

http://www.oxitec.com/press-release-oxitecs-genetically-engineered-mosquitoes-in-panama-pilot-achieve-over-90-control-of-the-mosquito-responsible-for-outbreaks-of-dengue-fever-and-chikungunya/

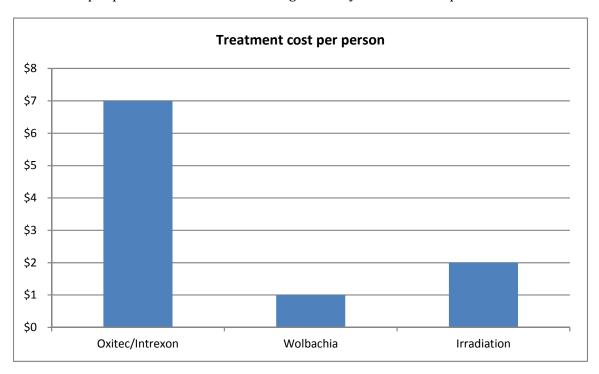
## Brazil plans to zap mosquitoes with radiation to halt spread of Zika virus

Authorities want to release sterilised males so that females lay inviable eggs, eradicating the Aedes mosquito that carries the virus blamed for surge in babies born with microcephaly

The Gates Foundation is promoting an alternative method to eradicate dengue and Zika: release mosquitoes infected with a bacterium, *Wolbachia pipientis*. This news should be particularly troubling to XON supporters because it appears the Foundation has switched their alliances away from Oxitec after previously supporting them<sup>20</sup>.

The method supported by The Gates Foundation has already been tried in Australia, Indonesia, Vietnam and Rio de Janeiro and appears to be very effective.<sup>21</sup> "In Australia, says O'Neill, it took 14 staffers one year to distribute mosquitoes over a 40-square-kilometer area, but since then local transmission of dengue has stopped." <sup>22</sup>

More attractive still, is the cost. The cost of the *Wolbachia pipientis* method is just \$1 per person<sup>23</sup> to implement in cities vs. \$7 per person PER YEAR for XON's genetically modified mosquitoes.



There are even more contenders with extremely cheap and effective solutions. For example, a Canadian company Greenlid developed a biodegradable bucket (cost \$1/bucket) that has already proven beneficial in Queensland, Australia<sup>24</sup>

<sup>&</sup>lt;sup>20</sup> http://www.sciencemag.org/news/2010/11/gm-mosquito-trial-strains-ties-gates-funded-project

http://www.nytimes.com/2016/02/05/world/australia/zika-virus-australia-mosquito-experiment.html? r=0

https://www.technologyreview.com/s/600893/bacteria-laden-mosquitoes-may-be-the-cheapest-way-to-stop-dengue-and-zika/

https://www.technologyreview.com/s/600893/bacteria-laden-mosquitoes-may-be-the-cheapest-way-to-stop-dengue-and-zika/



Reason #8: The FDA approval process will take years to complete

We think it will take <u>at least three years</u> before any conclusion can be reached on whether Oxitec's GM mosquitoes are suitable for US approval. While the FDA has talked about accelerating the approval process, the simple math (most of which is provided by XON/Oxitec) suggests that it will be years before there is even a chance of a commercial opportunity in the US.

XON received a Preliminary Finding of No Significant Impact (FONSI) on  $3/11/16^{25}$ . This is just the first step in a very long process. The FDA will now allow a 30-day comment period during which individuals can forward comments on the preliminary FONSI. We believe there will be at least another 30 days necessary for FDA to aggregate and address the comments for a total of 60 days before FDA publishes its final FONSI.

We estimate that the trial will take at least 25 months to complete, based largely on Oxitec's own assessment. The exhibit below is from Oxitec's "Draft Environmental Assessment for Investigational Use of Aedes aegypti OX513A" <sup>26</sup> as provided to the FDA.

- The "Preparation phase" is likely a month long process as Oxitec rears Ae. aegypti.
- The "Rangefinder phase" is another 8 weeks for Oxitec to release some OX513A males into the wild and monitor reproductive competitiveness with the wild A. aegypti in the area. Oxitec will also need to observe a 2x increase in the mortality of OX513A offspring.
- Finally, the "Suppression phase" will add up to 22 months to the trial process.

 $\frac{http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM487379.pdf$ 

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http://www.cbc.ca/news/canada/toronto/zika-greenlid-mosquito-trap-1.3468363

The trial is proposed in three phases:

- Preparation phase; which will involve Ae.aegypti rearing optimization in the HRU and environmental monitoring of the Ae.aegypti local population in the proposed trial location.
- Rangefinder phase; up to 8 weeks, which will involve the release of adult OX513A male
  mosquitoes up to three times a week at a constant release rate to determine more precisely
  the Ae.aegypti population in the proposed trial locations. This will also address the two
  primary objectives or goals of the trial; "does a male OX513A Ae.aegypti mosquito mate with

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Draft Environmental Assessment for Investigational Use of Aedes aegypti OX513A

more than one female of the local *Ae.aegypti* population and transfer the #OX513 rDNA construct to their resulting progeny" and "is there at least a 2-fold increase in mortality of these #OX513 rDNA construct-bearing progeny relative to local non-GE progeny before they reach functional adulthood."

Suppression phase: up to 22 months of sustained release of OX513A adult male mosquitoes
up to three times a week, the rate of which will be adapted dynamically during release to
achieve suppression of the local population of Ae.aegypti in the trial locations. This will allow
the secondary objective or goal of the trial to be assessed which is "does sustained release of
OX513A result in suppression of the local Ae.aegypti population by ≥50%, relative to the
comparator area that is not treated with the released OX513A". Monitoring of the release will
occur during and post releases using egg and adult trapping methods. The trial may be
concluded earlier if the trial objective is met.

Once the trial is complete, the data must be aggregated and results computed. For clinical trials, the National Academy of Science states "a moratorium of 18 months is generally appropriate before data are shared to allow trialists to carry out their analyses."<sup>27</sup> We conservatively estimate that Oxitec will need 9 months to compile its data/results.

Given the nature of Oxitec's application, it will be considered a Pioneering Application and be required to a New Animal Drug Application (NADA) with several components:

- 1. Chemistry, Manufacturing, and Controls
- 2. Effectiveness
- 3. Target Animal Safety
- 4. Human Food Safety
- 5. Environmental Impact
- 6. Labeling
- 7. All Other Information (AOI)

17

<sup>&</sup>lt;sup>27</sup> http://www.ncbi.nlm.nih.gov/books/NBK269030/pdf/Bookshelf NBK269030.pdf

The trial results will likely be used in to support the "Effectiveness" section of Oxitec's application. The FDA is required to approve or not approve an application within 180 days of submission. If the NADA qualifies as an administrative NADA, FDA is targeting a 60-day review/response time.<sup>28</sup>

# <u>Using this timeline, we estimate that the likely timeframe for an Oxitec approval would be August 2019, or roughly 3.5 years from now.</u>

	Actual	Months	Estimated
	date	required	<u>date</u>
FDA releases preliminary FONSI	Mar-16		
+ comment period and compilation		2	May-16
<u>Trial</u>			
Preparation phase		1	Jun-16
Rangefinder phase		2	Aug-16
Supression phase		22	May-18
Data aggregation, results computation		12	May-19
FDA review of application and potential approval		3	Aug-19

To compound the timing issues, at a Feb 10, 2016 hearing by Committee on Foreign Affairs titled, "The Global Zika Epidemic", Dr. Anthony Fauci (Director National Institute of Alergy and Infectious Diseases, NIH) stated that a Zika vaccine could be available by the end of 2017 (See 1:40:00 into the cited video).<sup>29</sup>

Dr. Fauci states that if Zika remains a "continually emergent situation and all things work well" and Phase 1 trials finish by the end of 2016, "you can go into an accelerated Phase 2a/2b, which if you do the math and the statistics, depending on the number of cases and how effective the vaccine is, from anywhere 6-8 months you may be able to show that it is in fact effective and safe. At that point, even though it would take maybe a few years to get the ultimate final stamp of approval, there is a mechanism of accelerated approval and accelerated access that you can implement if in fact you have a good safety profile and you have shown efficacy. You could conceivably have it by the end of 2017." (Source: <a href="https://youtu.be/ffTRyvbm8.8?t=6008">https://youtu.be/ffTRyvbm8.8?t=6008</a>

Reason #9: Do you really think we're going to release billions of genetically modified mosquitoes into the wild in any US city ever?

In a Panama trial, Oxitec released 4.3 million mosquitoes to "protect" 10 hectares of land (.04 square miles). Put simply, this is a tremendous amount of genetically modified mosquitoes to be released in such a small area.

If Oxitec were to "protect" a larger city, such as Miami, with similar ratios we estimate that they would need to release <u>6.2 billion</u> mosquitoes. To this, we say, "good luck convincing anyone that this would be a good idea." Does anyone really think that the city of Miami (or anywhere else for that matter) will agree to the release of over 6 billion genetically modified insects to protect from a disease that hasn't even been scientifically linked to any illness?

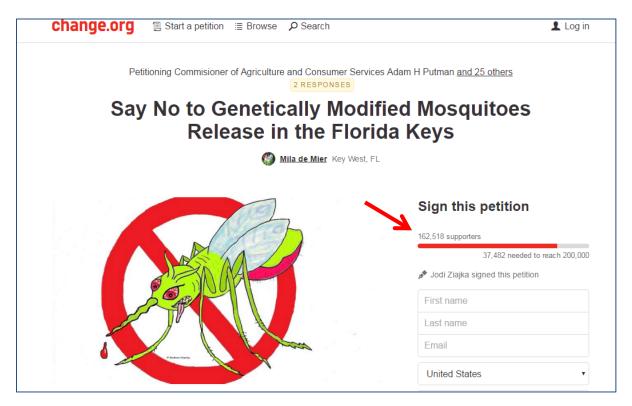
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http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052532.pdf

https://foreignaffairs.house.gov/hearing/subcommittee-hearing-global-zika-epidemic-emerging-americas

Miami city size (sq. mi.)	55.25
x Mosquitoes/hectare	430,000
x Hectares/sq. mi.	259
Mosquitoes required	6,153,168,743

We would also point to resident efforts in the Florida Keys to stop Oxitec's planned release. Change.org has a petition with over <u>162,000</u> signatures to "Say No to Genetically Modified Mosquitoes Release in the Florida Keys".<sup>30</sup> Efforts like these will likely make it politically more difficult for Oxitec to roll out its GM mosquitoes in additional areas.



Reason #10: The revenue opportunity in Brazil is tiny

XON has announced that they are building a new plant in Piracicaba, Brazil that will have the ability to "protect" 300,000 people. While this may seem like a lot, it is actually a tiny revenue opportunity for the company. Assuming that (a) the company is actually able to sign contracts with Brazilian municipalities for the Oxitec mosquitoes and (b) that they achieve pricing similar to that they have achieved in small scale trials, we estimate that the total revenue opportunity to XON is only around \$2 million.

People "protected"	300,000
Cost/person/year	<u>7.00</u>
Revenue opportunity	2,100,000

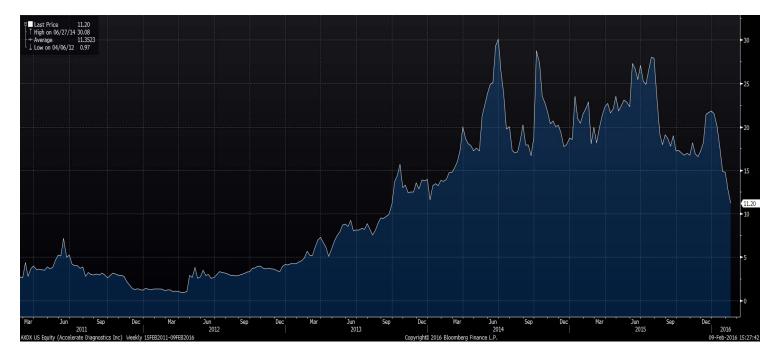
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https://www.change.org/p/say-no-to-genetically-modified-mosquitoes-release-in-the-floridakeys?recruiter=71063831&utm source=share petition&utm medium=facebook&utm campaign=autopublish&utm term=mob-xs-no src-reason msg

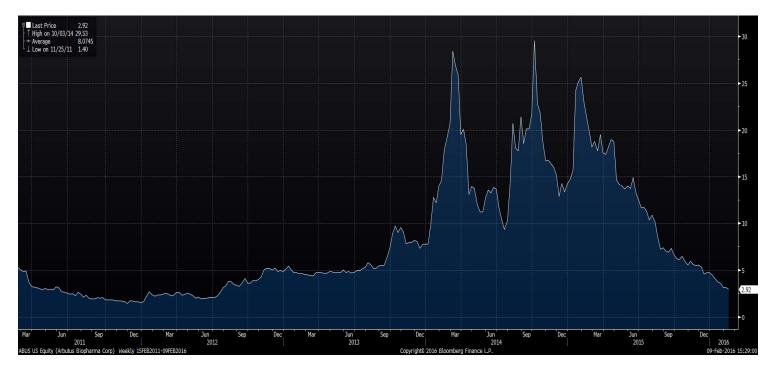
Reason #11: Ebola hype stock case study means that there is A LOT of downside to XON's share price once the hype subsides

A number of stocks soared as wild-eyed press reports about the ebola virus outbreak were plastered on the front pages of newspapers and websites in 2014. The two poster-children of this retail-investor-driven hype were Accelerate Diagnostics (AXDX) and Tekmira (TKMR). Both stocks rallied over 100% before crashing spectacularly once people realized that (a) the wild headlines would stop after people lost interest, (b) ebola would never generate any meaningful revenue for them and (c) the stocks were wildly overvalued.

## Accelerate Diagnostics (AXDX) → down >50%

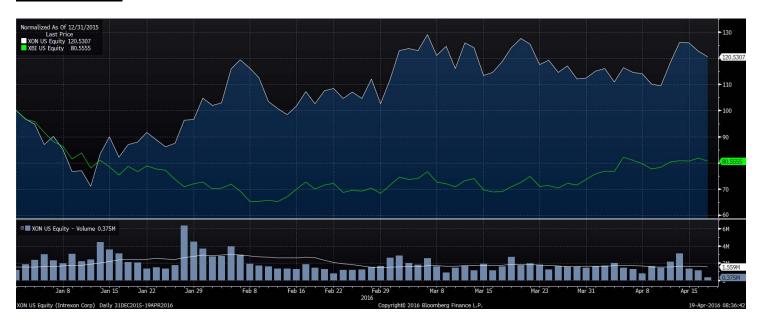


## Tekmira, now Arbutus (TKMR, now ABUS) → down 90%



While the biotech sector has crashed this year with the SPDR S&P Biotech ETF (XBI) down a whopping 20% YTD, XON shares are up 21%. We expect that, just based on the Zika hype receding, that XON stock will fall 40-50%+ as it catches up to the XBI index.

## XON vs. XBI ETF



To recap, ALL of the following need to happen for the Zika hype to be justified:

- 1) XON paid <7% of fair value for a company they acquired less than 6 months ago
- 2) A company that had never generated any revenue in more than a decade suddenly starts generating meaningful revenue
- 3) Zika needs to become an epidemic in line or greater than malaria and dengue fever, diseases that affect tens of millions of people per year and kill thousands
- 4) An actual scientific link needs to be established between Zika and microcephaly
- 5) An actual scientific link needs to be established between mosquito control and disease reduction
- 6) Trials being conducted for XON's technology need to complete and be successful
- 7) XON needs to develop, trial and commercialize GM mosquitoes for the other common mosquito types
- 8) XON needs to beat out competing technologies that are many multiples cheaper and equally effective

# Even if we ascribed a very generous 75% probability that each of the above would occur, that would leave a mere 10% chance of success.

## A tangent on comparable stock market promotions...

While we believe the analogy of Intrexon to Theranos is obvious once XON's technologies are analyzed, we thought it would also be instructive to draw a comparison between XON and 3D Systems (DDD), one of the great stock market promotions of this decade. As the below comparison illustrates, both Avi Reichental and RJ Kirk coupled their charismatic usage of the popular financial media with a portfolio approach of products, acquisitions, and partnerships to dazzle retail investors with consumer products, while at the same time impressing institutional investors with disruptive innovations with massive total addressable markets (TAMs) in the healthcare and industrials market places. In the case of both DDD and XON, the portfolio was so complicated that barely anyone could figure out what was real, and the promoters were so convincing that investors wanted to believe in the impossible.

Make no mistake, we share the view of many investors that RJ Kirk has had a successful career in past endeavors with big exits as the entrepreneur behind New River Pharmaceuticals and Clinical Data. With Intrexon, Kirk probably genuinely believed at one point that he had differentiated technology and that the opportunities he was chasing were extremely large and attractive. So why would such a successful individual engage in what we believe to be a large scale stock market promotion? We can't be sure why, and can only speculate that when he learned that the special technology he thought he had was actually undifferentiated, his strong drive for success may have led him down a slippery slope.

"Long story short we hear a story too good to be true... It ain't." - Aldo Raine

## All-time Great Stock Market Promoters: Avi Reichental (DDD) versus RJ Kirk (XON)

Promoter with track record of success in prior business endeavors	Avi Reichental – Successful 22 year career as senior Vice President at multi-billion dollar market capitalization industrial company Sealed Air (SEE)	RJ Kirk – Lawyer turned entrepreneur with successful previous exits (New River Pharmaceutical, Clinical Data) that made him extremely wealthy
Visionaries? CEO's true skillset is misperceived by the stock market	Viewed by the market as a technologist and visionary, Reichental's previous experience was in operations management	Viewed by the market as a healthcare industry guru and synthetic biology wizard, Kirk's previous experience was actually as a lawyer and dealmaker rather than as a doctor or scientist
Peak Valuation	• ~\$10 billion market capitalization	~\$8.5 billion market capitalization
"Secret Sauce", wonder technology that will supposedly disrupt established industries but has no track record of doing so	<ul> <li>3d Printing - In reality, technology has been around for prototyping since the 1980s without disrupting any large manufacturing applications</li> <li>Reichental generated several years of strong revenue growth at 3D Systems (DDD) via acquisitions rather than organic growth from internally developed technologies</li> </ul>	<ul> <li>Synthetic Biology – Intrexon has been around for more than 17 years and commercialized no meaningful products utilizing its own technology</li> <li>Other than related party transactions, nearly all reported revneue comes from selling cattle and cow embryros via recently acquired TransOva subsidiary. Nearly all "synthetic biology" public companies comparables have failed</li> </ul>
Examples of "Visionary" speak	<ul> <li>"I believe [3d printing] is the next big thing it could be as big as the steam engine was in its day, as big as the computer was in its day, as big as the internet was in its day I believe this is the next disruptive technology that is going to change everything."<sup>31</sup></li> <li>"This is only the beginning of a real movement when you have big companies like GE and Nike plowing billions of dollars into it, the train has left the station."<sup>32</sup></li> </ul>	<ul> <li>"I've been a biotech investor for 27 years, and Intrexon is by far the best thing I've ever seen." It is the "Google of the life sciences"<sup>33</sup></li> <li>"We all live today in the most poignant moment in history. And that the engineering of biology represents the greatest industrial vector that has ever been seen by mankind."<sup>34</sup></li> <li>"I think we have the broadest and deepest cell and gene therapy portfolio of any company in existence."<sup>35</sup></li> </ul>

https://www.youtube.com/watch?v=LRv4jp-hhBE

http://video.cnbc.com/gallery/?video=3000201438

http://www.forbes.com/forbes/2011/0314/health-care-randal-kirk-investor-biotech-grand-plans.html

http://www.cnbc.com/2016/01/29/stopping-the-spread-of-zika-with-mutant-mosquitoes.html

Repeat CNBC appearances with consumer product demonstrations  Reichental woos the CNBC team with his presentation of a toy bracelet from the Cube 3d printer:



 In his second CBC apperance of 1Q16, Kirk shows off the Artic Apple to CNBC anchors while waxing poetic on Oxitec's "cure" for Zika virus:



Products to capture the imagination of retail investors

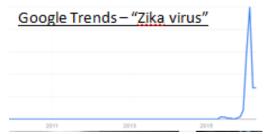
The Cube – 3D printer for hobbyists and children



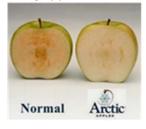
• The Sugar Lab – 3D printed sugar



 Oxitec – the "cure" for Zika, a buzzword virus that is trending in the popular media:



 The Artic Apple – genetically engineered non-browning apple:



Seemingly legitimate healthcare and industrial "growth" products with enormous TAMs to excite institutional investors • Healthcare - 3d printed medical devices:



 Healthcare – numerous early stages programs utilizing XON's UltraVector, Rheoswitch, and other XON technologies:



<sup>35</sup> http://video.cnbc.com/gallery/?video=3000502854

Seemingly legitimate healthcare and industrial "growth" products with enormous TAMs to excite institutional investors • Industrial- 3d printed airplane engines:



 Industrial – "partnering" with Dominion to explore conversion of biogas to Isobutanol



Blue chip companies touted as customers and partners, yet materiality of current and potential revenue from the blue chip companies is highly questionable



 For instance, DDD investor materials highlight Boeing as a key customer, yet as Citron Research revealed,<sup>36</sup> DDD was actually generating no revenue from Boeing.





 As we show in Part 2 of our report, minimal revenue is being generated from announced blue chip partnerships. Our analysis suggests that neither XON partners, nor XON itself, show any real indication of dedicating resources to these initiatives today

## Outcome

- Peaking at a ~\$10 billion market capitalization, DDD's stock fell 94% from the peak in January 2014 to the trough in January 2016 as the organic growth Reichental promised failed to materialize
- Reichental resigned in October 2015 and new management has since written off ~2/3 of the value of the acquisitions completed during his reign
- XON current sports a ~\$4.5bn market capitalization despite having generated substantial negative net income for each of the last 5 years (cumulative negative net income of \$370MM+) and negative free cash flow (cumulative negative FCF of \$220MM+, or negative \$440MM+ including acquisitions)
- The closet "synthetic biology" public comps we could find have all failed spectacularly:
  - GEVO (down 99%), AMRS (down 90%+), SZYM (down 80%), CDXS (down 70%), and MLBX (down 95%)

<sup>36</sup> http://www.citronresearch.com/wp-content/uploads/2013/02/DDD-final1.pdf

## SMART MONEY IS HITTING THE "EJECT" BUTTON AND LEAVING RETAIL INVESTORS HOLDING THE BAG

As the XON hype machine soars ever higher, the "smart" money is leaving as fast as they can.

### #1: Third Point recently sold all of their shares

Third Point invested in XON in 2011 before it even went public. As recently as the end of 2013, Dan Loeb<sup>37</sup> was comparing the company to Qualcomm, at the time a \$125 billion market cap company. With a track record of investment in XON longer than any other public markets investor, Third Point sold all of their shares  $\sim$ 50% below the 52-week high.

## #2: Krish Krishnan, RJ Kirk's right hand man, recently resigned

In March 2016, Krishnan surprised everyone by abruptly resigning from his position as Chief Operating Officer in *effective immediately*. To put it mildly, Krishnan has been an important colleague of Mr. Kirk's for a very long time. He served as an executive with Kirk at New River Pharmaceuticals and Third Security.

Krishnan knows Intrexon and Kirk better than anyone else. His abrupt departure, during such an "exciting" time for XON raises <u>huge</u> red flags, to put it mildly.

Less high profile, though still important, is the fact that Suma Krishnan, Krish's wife and the SVP of Product Development, left at the same time.

## #3: Executive revolving door

In addition to the departures of Krish and Suma Krishnan, XON appears to have had some trouble retaining key executives

Of the 13 executive hires that warranted an XON press release since late 2013, 3 have already departed the company, including, most notably Keith Canada, who was put in charge of the all-important UltraVector divison in September 2014 only to leave 9 months later with no explanation.

			Still	
<u>Date</u>	<u>Nam e</u>	<u>Title</u>	there?	<u>Tenure</u>
10/8/2015	Joseph Vaillancourt	Head of Environmental Sector	Υ	
9/28/2015	Corey Huck	SVP, Food Sector	Υ	
7/21/2015	Jack Bobo	Chief Communications Officer	Υ	
7/21/2015	Joel Liffman	SVP, Finance	Υ	
6/2/2015	Olivier Jarry	SVP, Consumer Sector	N	6 months
12/4/2014	Peter Emtage	VP, Synthetic Immunology	Υ	
9/5/2014	Keith Canada	VP, UltraVector	N	9 months
5/19/2014	Christopher Basta	VP, Investor Relations	Y	
3/17/2014	Samuel Broder	VP, Scientific and Public Affairs	Y	
3/4/2014	Nir Nimrodi	Head of Environmental Sector	Υ	
12/17/2013	Gregory Frost	Head of Health Sector	N	1 year, 8 months
11/18/2013	Peter Seufer-Wasserthal	VP, Business Development for Europe and Asia	Υ	
11/18/2013	Dana Di Fernando	Chief Information Officer	?	

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<sup>&</sup>lt;sup>37</sup> http://ftalphaville.ft.com/files/2014/01/Third-Point-Q4-2013-Investor-Letter-TPOI.pdf

## #4: Where are the smart money healthcare investors?

Some investors aren't hitting the eject button simply because they were never there in the first place. When looking at XON's investor base over time, there are a number of notable absences. Healthcare specialist funds that have backed many of the biggest biotech successes such as Orbimed, Brown Brothers, Healthcor and Deerfield are not shareholders. The people that actually know what they are talking about when it comes to healthcare have been smart enough to stay away from owning XON.

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