

**IN THIS ISSUE:**

<i>Our Best Weapon</i> .....	5
<i>A Brand-New Asset Class</i> .....	6
<i>Portfolio</i> .....	8

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# THE SUPERDRUG TO STOP SUPERBUGS

*How one tiny company is about to win the “bacterial arms race”*

by Ryan Cole

We’re losing the war — and most of us aren’t even aware we’re fighting one. Not on this battlefield.

Neglected by years of medical complacency, bacteria — once thought defeated, an antiquated nuisance like overstarched collars — are staging a furious comeback.

Without medical reinforcements, we’d be back to the bad old pre-penicillin days.

Luckily, that isn’t about to happen.

One company has developed a powerful new drug that can combat multiple germs, in multiple ways. I call it the new penicillin — a drug so powerful, it can eliminate a host of menacing threats in one fell swoop.

And it hasn’t come a moment too soon.

Not long ago it seemed like bacterial infection was a problem for another age. We thought we had infection beat. No longer would an open cut lead to a life-or-death prognosis... no longer was pneumonia the end for 60% of those who got it.

Not so fast.

Bacteria have been fighting back, in the form of new strains that are immune to our medicine. And, until very recently, they’ve been winning.

The truth is, with millions of infections and billions of dollars spent fighting them each year, drug-resistant germs are no longer a small subset of the medical world. They’re fast taking over.

Methicillin-resistant *Staphylococcus aureus* — or MRSA — is already responsible for well over half of all staphylococcus infections, and other drug-resistant germs are quickly catching up.

What’s more, even as the threat grows, our arsenal to combat it dwindles. For reasons we’ll see in a moment, “old” medicine is less and less effective, while new medical pipelines are drying up.

As a professor of epidemiology and environmental health sciences at the Bloomberg School of Public Health at Johns Hopkins, Ellen Silbergeld is an expert on drug-resistant germs.

She tells us the biggest health threats to emerge in the past 40 years aren’t new.

“E. Coli is not new, salmonella is not new, staph is not new. But what is new are strains of these old pathogens that are now resistant to almost all classes of drugs we can throw at them,” Silbergeld said.

“It’s a return of our old enemies in an untreatable form.”

In Europe, a recent study found up to half of all cases of blood poisoning from *K. pneumoniae* were resistant to carbapenems — the most powerful antibiotic on today’s market.

“The situation is critical,” said Marc Sprenger, director of the European Center for Disease Control and Prevention. “We need to declare a war against these bacteria.”

They’ve certainly already declared war on us. That’s why we need new weapons — like this new wonder drug — to stay

a step ahead of these infectious agents. There isn't a moment to lose.

## The Arms Race

Every year, 2 million American hospital patients contract an infection, and 100,000 of them die. It costs us over \$30 billion.

Even worse, approximately 1 out of every 300 people in the general population contract a drug-resistant infection each year — in high school locker rooms and fields, in college dorms, in malls, even swimming in the sea off the coast of Florida.

Every year, MRSA kills more Americans than infamous diseases such as HIV/AIDS. And, unlike AIDS, MRSA's growth is exploding across the world... and bringing along a variety of new playmates.

MRSA... multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB (tuberculosis)... drug-resistant pneumonia... vancomycin-resistant enterococcus (VRE)... the list goes on and on.

But, as so often happens, a solution has come along exactly when we need it. One tiny medical company has developed a powerful new superdrug — one that has shown remarkable efficacy against a host of drug-resistant bacteria, rather than just one.

Part of its success is because, instead of fighting bacteria in only one way, it attacks the germs on multiple fronts.

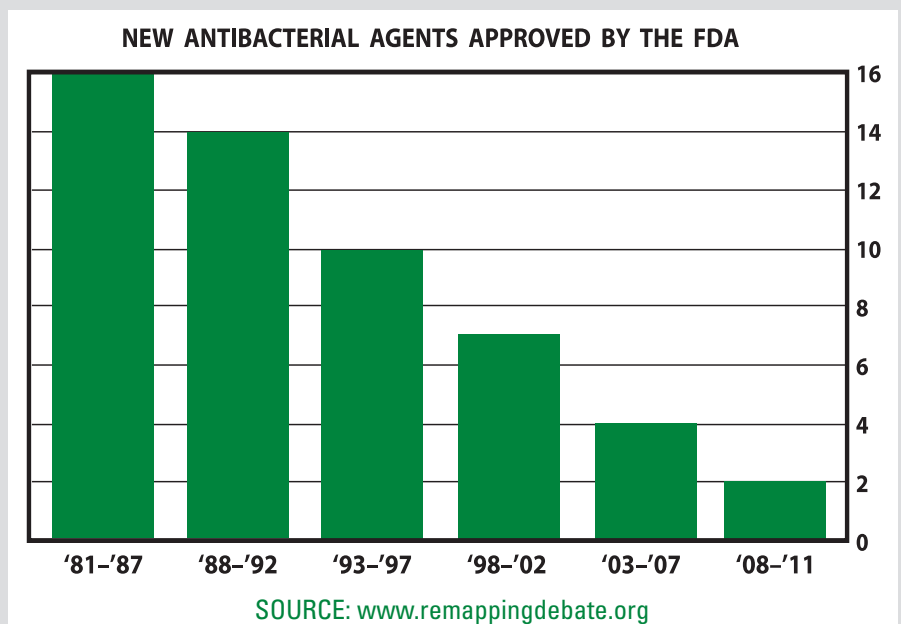
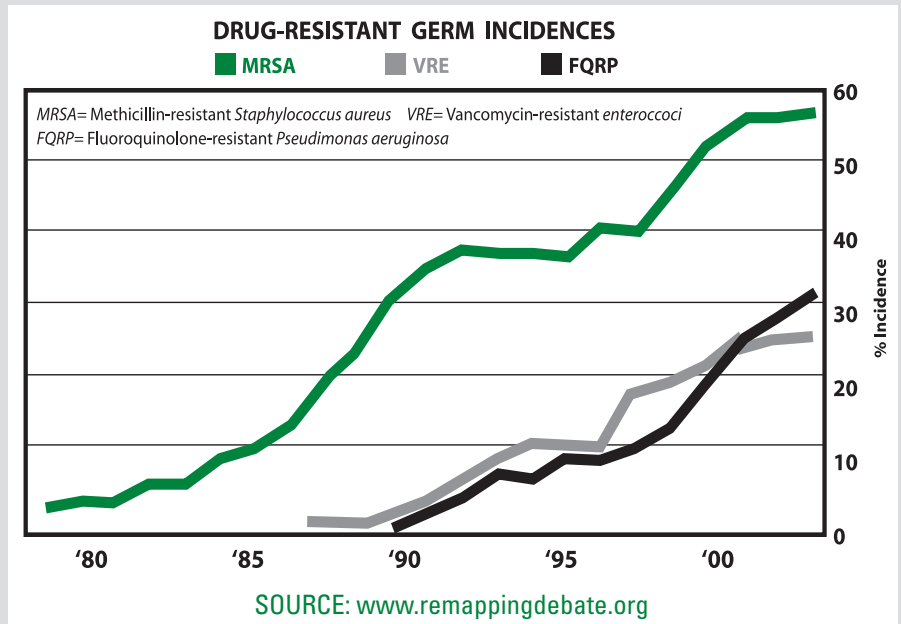
And, as investors and potential patients, the best news is the drug has already finished its second phase III trial — all that's left is to file with the FDA.

Given the positive results and lack of negative side effects, approval is likely. And we want to be holding this company when the big day comes.

This drug is, simply put, a game-changer — and a lifesaver. Once released

for public use, you'll see every hospital around the world stock up immediately.

You'll see news programs touting this new penicillin. And you'll enjoy an investing success of the sort you only find in the biotech world.



Indeed, sometimes just the whisper of a new drug is enough to send a stock soaring higher. When Cytogenix — a tiny biotech — had a few promising results with an avian flu vaccine, the stock flew up over 1,100%.

When the Heska Corporation — a veterinary drug company — discovered a vaccine to prevent the plague in mice, shares jumped 802% in less than a year.

After buying out a competitor in the middle of 2010, and then being given an Orphan Drug designation for a phase II drug that combats multiple myeloma blood cancer, XTL Pharmaceuticals has gone on a run that sees it up 642% today.

You may notice that these companies are scattered across the years, and across the biotech sector. There's a good reason for that.

Simply put, *you almost never see a small-cap biotech company take a revolutionary drug to market.* Most

blockbuster drugs come from big companies, such as Viagra from Pfizer, or Claritin from Shering-Plough.

When a small company does have a winning drug on its hands, it's usually bought out by giants well before full fruition — like Genentech by Roche in 2009, or Chiron by Novartis in 2005.

Small companies often take the cash in hand over the uncertainties of FDA trials and approvals.

That's why, when you have a small-cap with a winner in sight, you have to act immediately to grab your shares.

A buyout may still be on the way, but it will be for much, much larger sums. And, if there is no pharmaceutical giant that can bully its way to a majority share, you can do even better — multiplying your stake many fold.

You've seen what happens to companies that get anywhere close to

success from an important drug. But this opportunity — this is much bigger.

That's because there haven't been many drugs like this. This isn't for some small subset of a subset — such as plague infestations by mice, or sufferers of a specific type of blood cancer.

This is a drug for everyone — something that you or someone you know will use after it comes out.

It always feels like hyperbole to say this might save your life... but, in this case, it's justified.

If you contract staph... or pneumonia... or have a case of TB go active (one-third of all humans carry TB)... this new drug could very well help you see another day, quickly and in comfort... instead of spending months in a hospital with an uncertain prognosis.

The term "game-changer" doesn't do this drug justice. This drug could change the world as much as penicillin did.

But it will do it without the fanfare. It will feel like business as usual, if it comes out in time. Most folks will never know how close to the brink we've come.

## A Wily Cast of Characters

It is important to know what we're up against. So let's take a closer look at our foe, drug-resistant bacteria.

In his acceptance speech for the Nobel Prize in 1945, Sir Alexander Fleming, discoverer of penicillin, warned about its overuse.

He knew that bacteria were fast-adapting — and, if we weren't careful,



we'd have to face a new generation of germs that were immune to our attacks.

We weren't careful.

- We overprescribed antibiotics, exposing bacteria to our weaponry unnecessarily, and helping them develop resistance.
- We underdosed ourselves, often stopping a course of treatment once we felt better, unwittingly doing a fabulous job of killing regular bacteria, and leaving those that survived the onslaught to propagate and spread.
- In an effort to keep herds healthy and fat, we gave subtherapeutic doses of antibiotics to animals. By 1998, we had studies proving animal antibiotics were contributing to drug-resistant infections in humans, but that didn't slow us down. Today, one-quarter of all antibiotics are used in livestock.

The sad thing is, while we helped bacteria along with misusing our drugs... we've also helped it with dirty practices.

## Not So Antiseptic

Our hospitals are dirtier than you think.

According to a recent study done by Johns Hopkins, 26% of hospital medical cabinets are infected with MRSA and another 21% are infected with VRE.

A University of Maryland study found that 65% of doctors hadn't worn a clean lab coat for at least a week, making it a perfect way to transfer biological agents. Sixteen percent of doctors went

one step further and hadn't worn a clean lab coat for at least a month.

And that's not where the infectious spread ends.

Catheters and IVs are one of the most prevalent transmission vehicles for especially dangerous, blood-borne drug-resistant bacteria.

Blood pressure cuffs... surgical tools, especially more complex ones that are harder to clean... doors and floors and walls... they are all home to these superbugs.

In one case, a Texas VRE infection was traced back to an EKG wire. The wire had been exposed 38 days before, and lay in wait, uncleaned, to infect a burn victim over a month later.

But even the cleanest hospitals still struggle to contain drug-resistant bacteria.

That's because many of the same defenses that help drug-resistant bacteria defeat antibiotics are also useful for surviving cleaning.

Regular alcohol and antiseptics simply don't do the job. Harder stuff is needed, like bleach, or sporicidin-treated materials specifically designed to kill germs like MRSA.

Needless to say, that's a lot harder than just a spritz of alcohol gel. When those containers say they kill 99.9% of all bacteria, MRSA and other drug-resistant pathogens are the 0.1% that's often left behind.

All this would be bad enough... but bacteria have one last nasty trick up their sleeve.

## Sharing More Than Culture

Drug-resistant bacteria — all bacteria, in fact — don't simply evolve by the normal process of death for the weakest, with the strongest surviving.

They can also pass that strength along to each other.

When bacteria share a space, they have multiple ways to share DNA (the code that allows them to outsmart traditional medicine). They include:

- Sharing plasmids: small, circular extrachromosomal pieces of DNA that can encode multiple methods for resisting antibiotics. It is like handing a neighbor blueprints for a defensive moat.
- Transformation: a process similar to cell sex that allows more than one bacteria to share DNA with offspring.
- Dead germs: bacteria can scavenge the DNA. It is like taking gold off corpses in a battlefield.
- Transposons — sometimes called "jumping DNA": strands of DNA that can get shot out from one bacteria and float around until they find another bacteria to join.

As you can see, these aren't the simple creatures we often think them to be. These are actually very sophisticated machines, with multiple methods of sharing DNA and supercharging evolution.

In fact, the most worrying thing about this may be that different species of bacteria share between each other in

this exact way — so while staph may currently be susceptible to vancomycin in many cases, after a few generations with resistant enterococcus, staph will usually pick up resistance.

That's part of the reason any single human can be such an incubation ground for infection. Once a single germ is in, it's easier for others to invade. And, once they all get together, they start sharing drug-resistance.

It's not unusual for one person, undergoing treatment for infection, to find that one drug after another after another starts with promise, and ends in failure, as the bacteria learn from each other. These cases often end in amputation or death.

And of course, we do our best to keep such a person's environment sterile and stop disease from spreading... but, inevitably, some germs escape into the commons.

That's how MRSA spread from hospitals in 1961 to its prevalence throughout the world today (more people get MRSA out of hospitals than within now). And it's why we know, as bad as the current superbugs are, there are already worse strains lurking.

But enough about the nefarious means by which bacteria share their drug-resistant traits.

What makes them drug-resistant in the first place? And how do we fight them?

## Higher Walls and Thicker Skins

The simplest way for bacteria to obtain drug-resistance is to build hardier cell walls.

In practice, that means a few things:

- Bacteria reduce the permeability of their cell walls, making it harder for drugs to get in.
- Bacteria reduce the number of “doors” into the cell, most especially the hook-ups used by antibiotics to gain access.
- Bacteria introduce guards to their cell walls, so if any antibiotics get in, they are stopped and, in some cases, destroyed or spit back out.

Many drugs work by binding to a specific target on a bacteria, which the bacteria can defend by changing the target. Drugs that took us decades to develop, a bacteria can circumvent in a few quick generations.

And bacteria are now producing enzymes that absolutely decimate antibiotics like penicillin. These enzymes can destroy our medicine before they have a chance to do a thing.

But these dangers are being neutralized, right now. Allow me to introduce oritavancin, a product of **The Medicines Company (MDCO:NASDAQ)**.

## Our Newest, Best Weapon

Antibiotics work in one of two ways: They either work against a bacterial cell wall, exposing its insides to the elements, or they interfere with protein synthesis and the inner workings of germs.

Oritavancin does both. It weakens the cell walls, while simultaneously disrupting the inner workings of bacteria.

This fact doesn't just make it a more effective killing machine, it also makes it harder for bacteria to combat.

If a strain solves one part of the puzzle, it still probably won't solve the other — giving oritavancin both a great success rate and better staying power in this arms race.

In trials, oritavancin has already proven its worth.

Methicillin and vancomycin — the two drugs that are still the most successful, though even they are facing resistant bugs — do no better than oritavancin against common bugs.

Even better, in strains known to be resistant to methicillin and/or vancomycin, oritavancin retains its curing power. It's proven itself the best successor out there.

Simply put, oritavancin is the only drug for which bacteria currently have no defense.

Unlike most drugs, oritavancin isn't metabolized by the body. That means two things.

First, it remains in the body longer. That's why, unlike most antibiotics, patients don't need an entire regimen — a single high dose will do it. Oritavancin is unique in this way.

Second, no more underdosing. That means there is no more culling strong bacteria from weak. All are killed in the early going, before they have a good chance to recover and repropagate as a resistant strain.

Oritavancin can be administered once... and then patients can leave.

No more clogging hospital beds. No more forgotten meds. One dose and the patient is done.

## A BRAND-NEW ASSET CLASS

Last month, I met with some of the biggest movers and shakers in an entirely new asset class.

It's the result of the JOBS Act, and it's called crowd funding. In simple terms, it's an opportunity for anyone to be an angel investor or a venture capitalist.

As soon as the SEC figures out the rules and regulations for this new market over the next 270 days, small businesses will be able to register with portals, undergo a vetting process, and then get investments from ordinary citizens, in any amount, up to \$100,000 (but usually much smaller).

There are a number of opportunities in this new space — and starting a new small business isn't anywhere near the best.

At my meeting, I talked to...

- CEOs of current crowd-funding portals like Rocket Hub and IndieGoGo.
- Leaders and founders of vetting organizations.
- Future broker-dealers — those who will perform the actual security exchanges.
- Entrepreneurs trying to figure out the best angle to grab the most profit from this new market.

I'm doing the same thing; I want to find the best ways for us to get in on the ground floor of this brand-new asset class. That's why I went to New York last month... and it's why I'll be traveling even more over the coming months.

Simply put, it's rare an entirely new exchange emerges... and rarer still you can grab a founding piece of it.

That's the sort of opportunity I see developing here. It isn't easy to navigate these new waters, which is why you won't see this sort of reporting many places.

But you'll see it here. And, as the dust settles and the opportunities emerge, we're going to be ready to grab them.

It's a brave new world. Let's own a founding piece of it.

This is huge — not only because it saves hospitals a ton of money, but also because it is a safer, easier way to treat infection.

However, the second aspect of oritavancin's workings within our body might be even more significant.

Since the body doesn't metabolize oritavancin, it never enters the liver (or other organs).

That means it doesn't do the damage that other drugs often do. And it won't interfere or have bad side effects when combined with other drugs, especially important for the weakest, least healthy members of society that are most susceptible to these superbugs.

So not only is it more potent than other antibiotics... not only is it easier to take... but oritavancin is safer too.

Ironically, at one point, this aspect of oritavancin was considered a possible weakness.

You see, the antibiotic lives inside our microphages — an important component of our immune system.

That's why the FDA requested further study after an earlier phase III trial. It was true that oritavancin worked, and it didn't have any adverse effects... but the FDA wanted to be absolutely sure that it wasn't going to interfere with the workings of our immune systems.

The just-completed phase III trial shows exactly that — there have been no adverse effects in human trials.

The bottom line is oritavancin is safer than other antibiotics. It's the easiest to

administer. And it's also the most powerful — attacking bacteria in two ways, and doing so with overwhelming force.

Most importantly, though, the drug works against MRSA, strains of bacteria immune to vancomycin, pneumonia and a host of others.

You can see why I'm so excited about this opportunity. We've got a chance to jump on the bandwagon before it leaves the station — and, with so much need and so many benefits, this is a bandwagon we want to be on.

But, when we invest in oritavancin, we don't just get a superdrug...

## A Leader in Critical Care

The Medicines Company, the biotech firm that purchased oritavancin in 2009, isn't a one-trick pony.

Its business is focused on all aspects of critical care, and it has a number of products already being used in hospitals today.

- Angioplax: an anticoagulant doctors use when performing heart surgeries.
- Cleviprex: a medicine that controls blood pressure in critical situations like ER emergencies.
- Congrelor: an anti-platelet drug currently in the middle phases of testing.
- A number of other drugs in the early phases of study, with the chance to help those with heart disease, and those undergoing surgery.

And, of course, oritavancin. Make no mistake — oritavancin is the superstar of the group, with the chance to have the greatest impact on the widest segments of society.

For the moment, it's only being studied for skin and subcutaneous infections... but,

once the FDA gives its approval for those cases, we can expect rapid development for other uses.

The Medicines Company would be a solid investment even *without* oritavancin. Thanks to the success of its other drugs, it has strong financials: a 26% profit margin, a P/E ratio of only 8.5, and a price-to-book just a hair over 2.

In other words, even if some new surprise study came out and doomed oritavancin, *we'd still be getting a great biotech at a great price.*

Factor in the strong likelihood that oritavancin will soon be the first and last line of defense against the world's superbugs — and we're looking at the sort of winner most investors never dare dream of.

I'm very excited to add The Medicines Company to the *Small Cap Insider* portfolio. I hope you are as well. ■

From the Inside,



Ryan Cole  
Editor, *Small Cap Insider*

### ACTION TO TAKE:

**Buy The Medicines Company (MDCO:NASDAQ) up to \$22.**

### IMPORTANT INFORMATION

**Your June issue will be published online on Tuesday, May 29, 2012.**

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## *Small Cap Insider Portfolio*

STOCK NAME	STOCK SYMBOL	ISSUE/ALERT RECOMMENDED	ENTRY PRICE	DIVIDEND YIELD	COMMENTS
Zumiez	ZUMZ	February 2012	\$27.66	–	A nod to Sam Walton — Buy under \$30
3D Systems (1 <sup>st</sup> Half)	DDD	Weekly Alert, 2/24/12	\$24.15	–	A piece of the 3-D printing pie — Buy under \$22
3D Systems (2 <sup>nd</sup> Half)	DDD	Red Alert, 3/6/12	\$21.71	–	A piece of the 3-D printing pie — Buy at \$22 or less
Poseidon Concepts	PSN:TSX	April 2012	\$14.00	7.30%	A niche player with a virtual monopoly — Buy under \$17
Ridgeline Energy Services	RLE:TSX-V	April 2012	\$1.09	–	Fracking's solution to dirty water — Buy under \$1.25
GasFrac Energy Services	GFS:TSX	April 2012	\$6.93	–	The way fracking will be done tomorrow — Buy under \$7
Medicines Company	MDCO	May 2012	NEW	–	Developer of game-changing superdrug — Buy up to \$22

## *Special Report Recommendations*

STOCK NAME	STOCK SYMBOL	DATE OF FIRST RELEASE	ENTRY PRICE	DIVIDEND YIELD	REPORT RECOMMENDED
Glu Mobile	GLUU	11/28/11	\$2.85	–	The Four Best Tipping-Point Trade Recommendations for Cashing In on the 'Protocol 5' Revolution
Majesco Entertainment Company	COOL	11/28/11	\$2.73	–	The Four Best Tipping-Point Trade Recommendations for Cashing In on the 'Protocol 5' Revolution
Chyron Corporation	CHYR	11/28/11	\$1.35	–	The Four Best Tipping-Point Trade Recommendations for Cashing In on the 'Protocol 5' Revolution
Avid Technology, Inc.	AVID	11/28/11	\$6.94	–	The Four Best Tipping-Point Trade Recommendations for Cashing In on the 'Protocol 5' Revolution

## *New Growth Investor Portfolio*

STOCK NAME	STOCK SYMBOL	ISSUE/ALERT RECOMMENDED	ENTRY PRICE	DIVIDEND YIELD	COMMENTS
ProShares Ultra MSCI Emerging Markets (holding 50%)	EEV	June 17, 2011 Alert	\$32.07	–	New strategies for new market dynamics — Buy up to \$33.50
Green Dot Corporation	GDOT	August 2011	\$36.20	–	Court-ordered profits — Hold
Dunkin' Brands Group	DNKN	September 2011	\$28.60	–	Move over, Starbucks — Use a Buy-Stop Order above \$28.60
Gannett Co., Inc.	GCI	October 2011	\$9.16	2.70%	"Rich Media" — Buy at \$9.25 or better
LinkedIn Corporation	LNKD	November 2011	\$78.50	–	Network connection — Set initial stop order at \$61.20