

# Why I'm Short Exact Sciences (EXAS)

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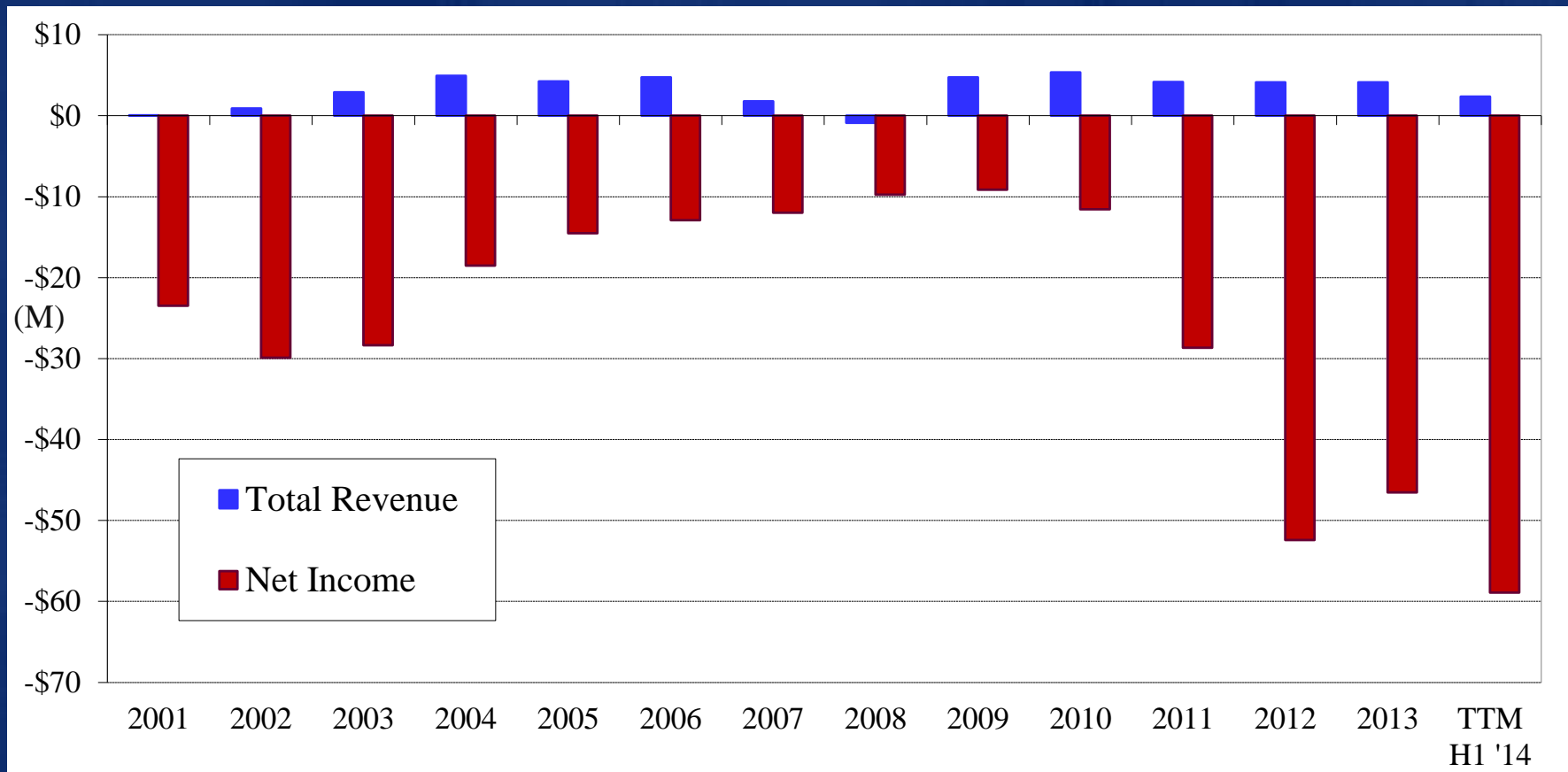
# Exact Sciences' Stock Has Doubled in the Past Year – And Has Risen ~60x Since Its 2008 Lows

## Exact Sciences Since Its IPO



# Exact Sciences Has Never Generated Meaningful Revenues and Its Losses Are Accelerating

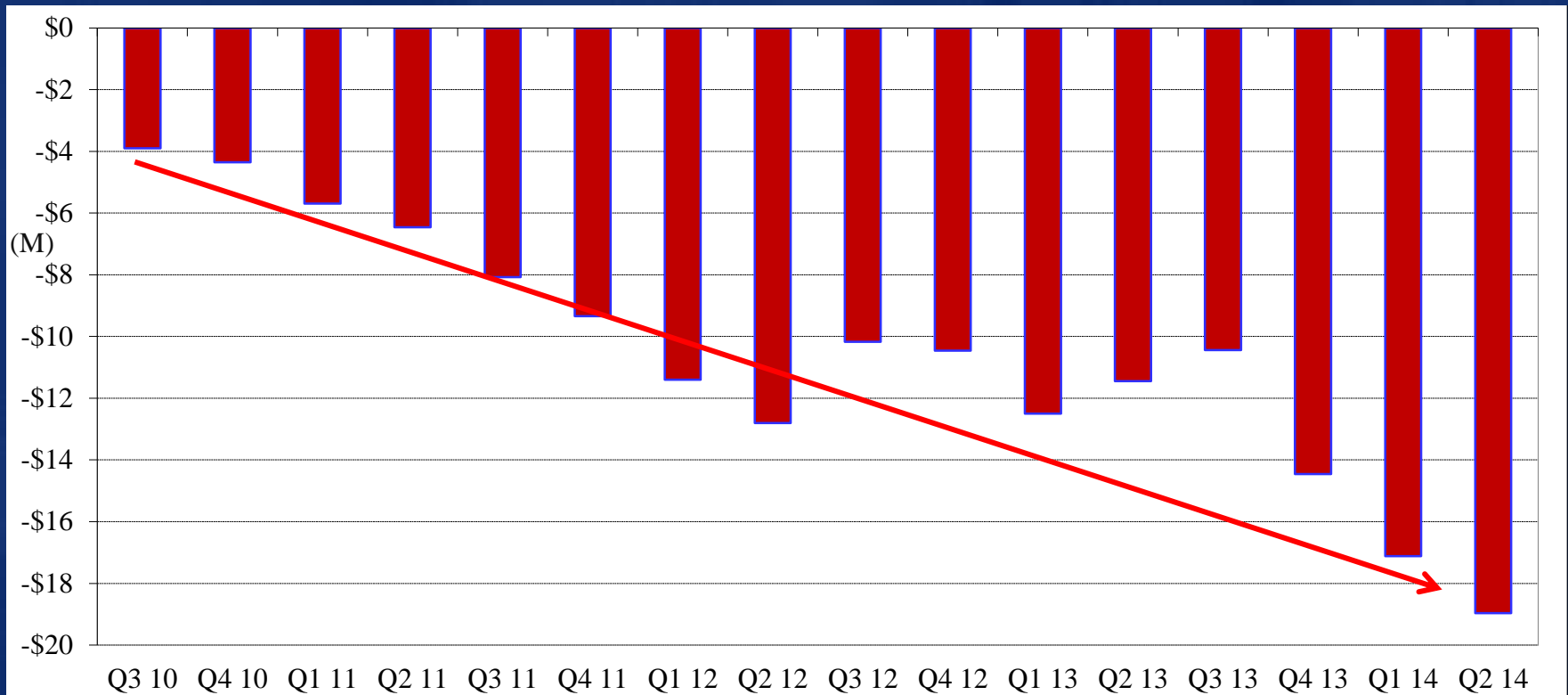
- In Q2 '14, revenues were zero and net loss was \$19.4 million



# Exact Sciences' Quarterly Cash Burn Is Rising – And Will Intensify as the Sales Force Is Hired

- Cash burn could approach \$100 million in 2015

## Free Cash Flow



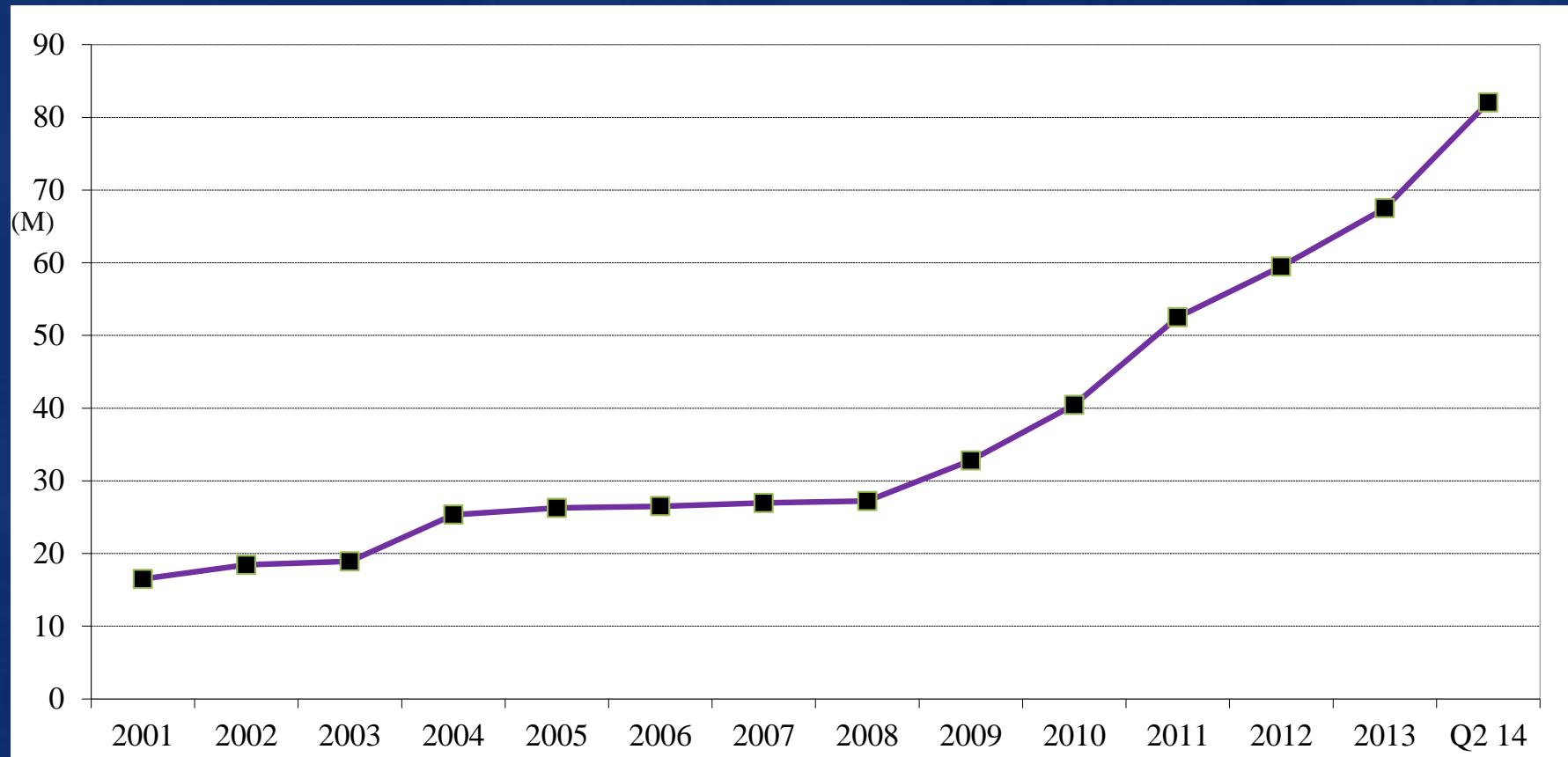
FCF is operating cash flow minus cap ex

Source: CapitalIQ.

# To Fund Its Losses, Exact Sciences Has Issued More and More Shares, Diluting Shareholders

- The share count has more than tripled in the past six years

Diluted Shares Outstanding





# Overview of Exact Sciences

- Exact Sciences is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer
- It has developed a noninvasive DNA screening test, Cologuard, which was recently approved by the FDA, that detects colorectal cancer and precancerous polyps
- I prefer to short the stocks of fraudulent and/or evil companies, but that's not the case here. I obviously hope Cologuard helps reduce the death toll from this terrible disease – I just don't think it's likely to (certainly not to the extent that's reflected in the share price)



Sample Processing Lab



# Colon Cancer Is the Second-Leading U.S. Cancer Killer

- “The most preventable, yet least prevented cancer.” – Journal of the National Cancer Institute

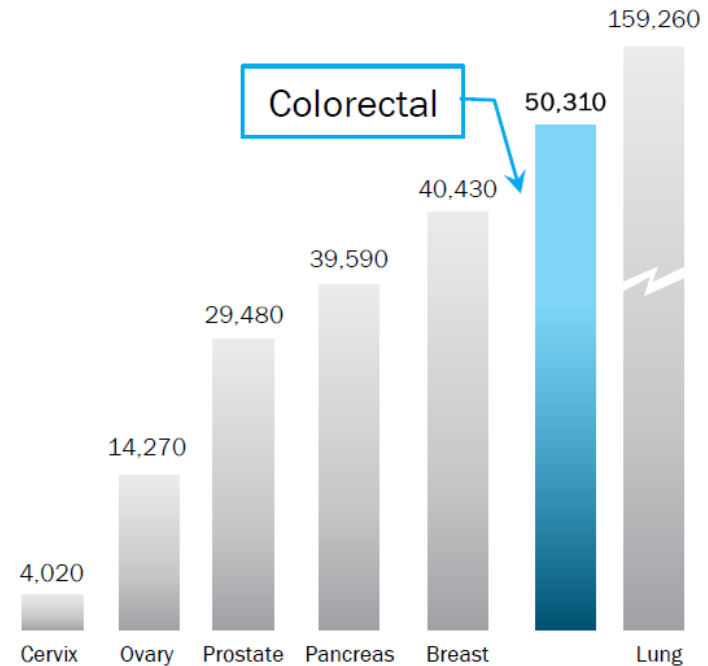
**136,830**

new U.S. cases

**50,310**

U.S. deaths

Annual U.S. cancer mortality



# Early Detection Is Critical



**9** out of **10**

*Diagnosed early stage (I-II)*

*Survive 5 years*



**1** out of **10**

*Diagnosed Stage IV*

*Survive 5 years*

\* Other studies show 74% and 6%, respectively.

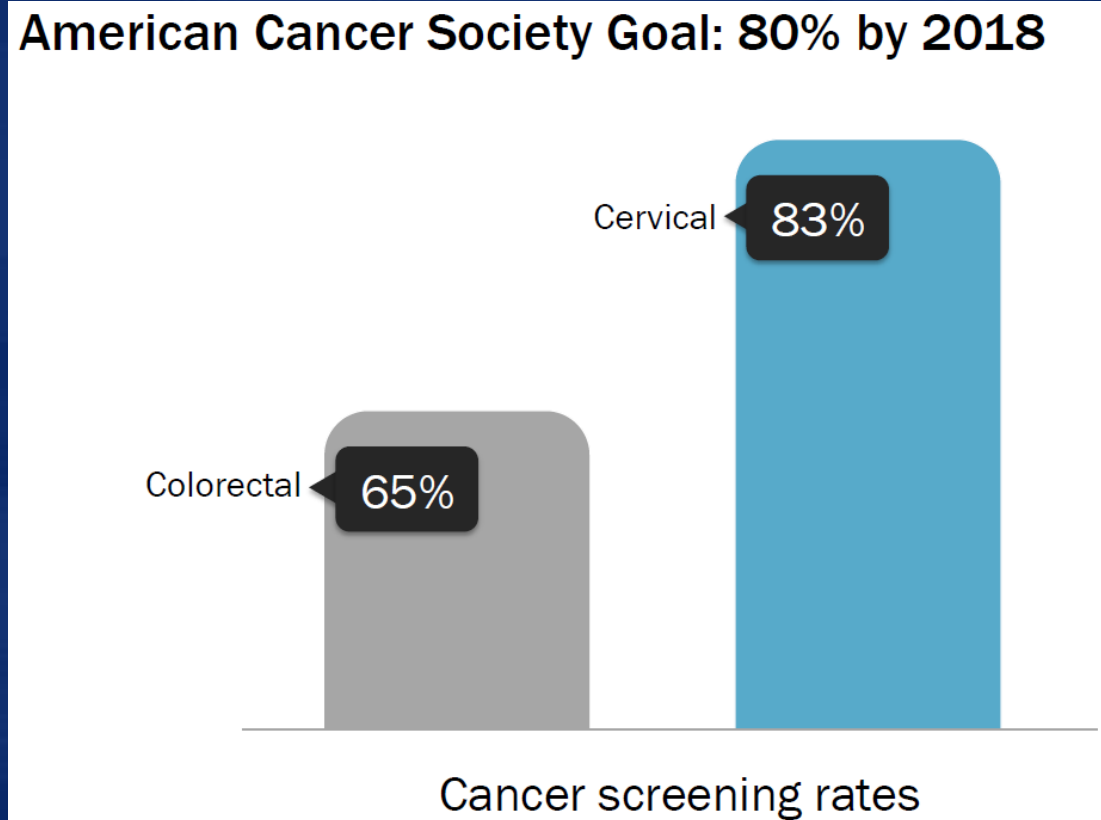
Source: Exact Sciences annual meeting presentation, 7/22/14.

# Best Practice Is a Colonoscopy

- The Centers for Disease Control and Prevention and the American College of Gastroenterology recommend a colonoscopy every 10 years, beginning at age 50, for average-risk men and women ages 50-75
  - During a colonoscopy, physicians use a flexible, lighted tube (colonoscope) to look at the interior walls of the rectum and the entire colon. During this procedure, samples of tissue may be collected for closer examination, or polyps may be removed. Colonoscopies can be used as screening tests or as follow-up diagnostic tools when the results of another screening test are positive.
  - Colonoscopy also is used as a diagnostic test when a person has symptoms, and it can be used as a follow-up test when the results of another colorectal cancer screening test are unclear or abnormal.
- But a colonoscopy is expensive, time-consuming, invasive, not available everywhere, risks complications, and uncomfortable – both the preparation as well as the actual procedure
- In lieu of a colonoscopy, “patients should be offered an alternative CRC prevention test (flexible sigmoidoscopy every 5–10 years, or a computed tomography (CT) colonography every 5 years) or a cancer detection test (fecal immunochemical test for blood, FIT).”

# Current Screening Is Poor

- Only 65% of people who should be screened are, a major reason why 60% of colon cancers detected are already in late stage



# Comedian Dave Barry's Description of Preparing for a Colonoscopy

Then, on the day before my colonoscopy, I began my preparation. In accordance with my instructions, I didn't eat any solid food that day; all I had was chicken broth, which is basically water, only with less flavor. Then, in the evening, I took the MoviPrep. You mix two packets of powder together in a one-liter plastic jug, then you fill it with lukewarm water. (For those unfamiliar with the metric system, a liter is about 32 gallons.) Then you have to drink the whole jug. This takes about an hour, because MoviPrep tastes -- and here I am being kind -- like a mixture of goat spit and urinal cleanser, with just a hint of lemon.

The instructions for MoviPrep, clearly written by somebody with a great sense of humor, state that after you drink it, "a loose watery bowel movement may result." This is kind of like saying that after you jump off your roof, you may experience contact with the ground.

MoviPrep is a nuclear laxative. I don't want to be too graphic, here, but: Have you ever seen a space shuttle launch? This is pretty much the MoviPrep experience, with you as the shuttle. There are times when you wish the commode had a seat belt. You spend several hours pretty much confined to the bathroom, spurting violently. You eliminate *everything*. And then, when you figure you must be totally empty, you have to drink *another* liter of MoviPrep, at which point, as far as I can tell, your bowels travel into the future and start eliminating food that you have not even *eaten* yet.

After an action-packed evening, I finally got to sleep. The next morning my wife drove me to the clinic. I was very nervous. Not only was I worried about the procedure, but I had been experiencing occasional return bouts of MoviPrep spurtage. I was thinking, "What if I spurt on Andy?" How do you apologize to a friend for something like that? Flowers would not be enough.

– Dave Barry, Miami Herald, 2/22/08

# Does This Look Like Fun?



# Cologuard Is an Alternative to the Current Screening Test, FIT

- In a ~10,000 patient study published in the New England Journal of Medicine, Cologuard was significantly more likely to detect colorectal cancer and precancerous polyps vs. the current blood-based test, FIT:
- This isn't surprising since Cologuard includes a FIT test and then also tests for nine DNA markers

	Cologuard	FIT
Cancer Sensitivity	92%	73%
Advanced Adenoma Sensitivity	42%	24%



# Everything That Could Go Right, Has Gone Right for Exact Sciences In Recent Years



- Positive study results
- FDA approval
- Generous preliminary reimbursement

As a result, the stock, with a \$2 billion market cap, is priced for perfection so anything short of rapid adoption and the stock will get clobbered

# So Why Am I Short the Stock?

- 1) It's not clear that Cologuard is so much better than the FIT test
- 2) There's a big false-positive problem
- 3) It's *23 times* more expensive than the FIT test (~\$22 vs. \$502), which has been around for a long time and is widely known, trusted, available, and covered by all insurers
- 4) Cologuard is much "messier"
- 5) Competition is looming
- 6) Commercial payor adoption may be slower than anticipated

For all of these reasons, I think adoption of Cologuard will be gradual, which isn't what is priced into the stock

# Exact Sciences' Study Likely Understates the Sensitivity of the FIT Test

- The comparison FIT used in the DeeP-C (Cologuard) study was an inferior Polymedco FIT test, which uses a single stool sample (typically only used by physicians when they want immediate results, such as in the ER or in their office after a prostate exam)
- A more fair, real-world study would have used a leading FIT test such as InSure, which is done in the home (as is Cologuard), which uses two stool samples and claims an 87% detection rate
  - Other studies of FIT tests show lower detection rates (in the 66-75% range, consistent with the 73% in the DeeP-C study), but these studies used older and/or single-stool FIT tests
- The CDC recommends a FIT test with “three consecutive stool samples,” done annually; in contrast, Cologuard uses a single sample and will likely be given only once every three years
- A study of Cologuard once every three years vs. a two- or three-stool-sample FIT test once a year for three years hasn't been done, so it's not clear whether, in a real-world setting, how much better the detection rate is for Cologuard vs. FIT
  - Since Cologuard includes a FIT test, it can't have lower sensitivity...but it might not be much higher

# A False Positive Problem

- Unmentioned in Exact Sciences' investor presentation is the fact that Cologuard has a false positive rate of 13.4%, *five to ten times* that claimed by the InSure FIT test (2%) and nearly three times the 5% rate found in other studies (including the Polymedco test used in the DeeP-C study)
- This is a major concern for many doctors because it means that for every 7-8 patients for whom they prescribe the Cologuard test, the results come back with a false positive
- This means many unnecessary colonoscopies, but more importantly the doctor has to call the patient and say, "I have some bad news: the test you just took indicates that you may have colorectal cancer, the second-deadliest form of cancer. But it might be a false positive, so let's schedule a colonoscopy to be sure"
- The patient, of course, only hears the first sentence and panics, thinking "I HAVE CANCER AND I'M GOING TO DIE!!!" and has to endure true agony and terror until they can get a colonoscopy and learn that, "Ooops, the test was wrong and you're fine"
- Exact Sciences' response:
  - If the FIT test is given each year for three years, the 5% false positive each time adds up to 15%+ every three years, which is higher than Cologuard's
  - Nearly half of the positive results from the Cologuard test are characterized as false but nevertheless the subsequent colonoscopy shows nonadvanced adenoma (small polyps), so the patient having the colonoscopy was beneficial
  - In short, the trade-off of higher detection for more false positives is worth it

# Cologuard Is 23x More Expensive Than the FIT Test



- The Centers for Medicare & Medicaid Services recently approved preliminary reimbursement for Cologuard at \$502, 23x *higher* than the ~\$22 cost of a FIT test
- In this era of the Affordable Care Act, insurers and doctors are much more sensitive to the cost of expensive tests than they used to be
  - Doctors are increasingly evaluated on the number and cost of tests they order

# Cologuard's “Ick” Factor (1)

- Cologuard requires significantly more fecal handling than FIT, which could lead to significant resistance by patients
- FIT requires nothing more than a quick poke of the stool:
- In contrast, Cologuard requires patients to fill a large container with their poop, a smelly, messy, disgusting process:
- Do you *really* think Americans (and their doctors) will embrace this “poop-in-a-bucket” model???
- One expert I spoke with said:
  - “Twenty years in clinical medicine taught me that contact with stool is the third rail of patient compliance. Collection, storage – it ain’t gonna happen.”
- Two earlier versions of the Cologuard test were busts
  - Peak quarterly revenues of <\$250,000 and ~700 tests a decade ago





# Cologuard's "Ick" Factor (2)

- This photo in Exact Sciences' presentation doesn't really show how large the container is:



- It is 1.4 liters or 5.9 cups, more volume than this large measuring cup:
- After the patient poops in the container, he/she must poke it with a brush (for the FIT test), then pour 250ml of preservative into the container, seal and pack it, and mail the box to Exact Sciences' lab
  - This is much more handling than is required by the FIT test, which can be mailed in a regular envelope
- Exact Sciences' response:
  - It's not that much more handling and patients will do what their doctors ask them
  - Cologuard compliance will, in fact, be higher than FIT because, unlike FIT, which doctors "hand out like candy" and have no way of tracking and following up with patients, Exact Sciences has a phone bank to: a) call patients to get their address and mail them the Cologuard kit; b) follow up with phone calls; and c) if the patient still doesn't send it in, let their doctor know so he/she can follow up



# Competition Is Looming

- An oral diagnostic (a camera-in-a-pill called PillCam Colon, made by Given Imaging, which was acquired by Covidien earlier this year) was approved the FDA in February (and was already available in more than 80 countries)
- A blood-based diagnostic (Epi proColon Assay) is approved Europe and in the approval process in the U.S.
- Clinical Genomics of Australia has also developed a blood-based test focused on two biomarkers of non-Sereptin9 methylated gene products
- Other blood-based diagnostics with materially better sensitivity for pre-cancerous polyps are under development, so Cologuard's day in the sun will likely be limited (a critically important factor given that EXAS's valuation is entirely dependent on Cologuard's anticipated success many years into the future)
  - A recently published article ([www.ncbi.nlm.nih.gov/pubmed/23704278](http://www.ncbi.nlm.nih.gov/pubmed/23704278)) highlights early development of a microRNA biomarker diagnostic test using a simple blood draw that has an 81% sensitivity in pre-cancerous colon cancer detection (vs. 41% for Cologuard) and 92% sensitivity in detection of colorectal cancer (same as Cologuard)
  - This test uses a single miRNA marker; the research group is looking at a number of other microDNA markers to further enhance the sensitivity and it is highly probable that other markers will also be found to be effective
  - This research is garnering significant attention within the scientific community, but is currently unknown by the financial community



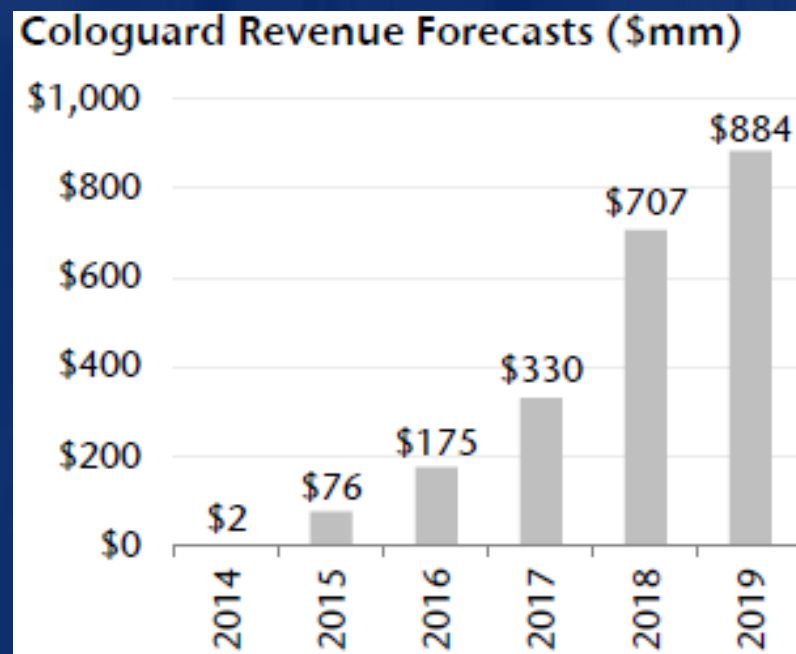
All of these alternatives raise questions about the long-term potential of Cologuard and underscore the exaggerated valuation of EXAS

# Commercial Payor Adoption May Be Slower Than Anticipated

- Aetna recently announced that it does not cover Cologuard and views the test as experimental and investigational
  - “Comparative-effectiveness studies are now needed to clarify the role of stool DNA testing with respect to programmatic screening with other test options. Only through a better understanding of other key factors, such as the screening interval, adherence, cost, and diagnostic evaluation of positive results, can we determine the appropriate place for stool DNA testing on the screening menu.”
- Maxim Group report (8/22/14):
  - Commercial payors are likely to use a more market-based approach to reimbursement. The government recently made steps toward adopting a more market-based approach to reimbursement. While those changes do not take effect until 2017, we anticipate that commercial payors will selectively be more proactive in reimbursing new tests at what they view as market rates and not based on the methodologies currently used by CMS. The Cologuard is in competition with \$20-\$30 FIT tests, as well as emerging blood-based tests, which creates a challenging market environment, in our view.
- More than 60% of CRC patients are over 65 years old so commercial payors have historically avoided reimbursement of screening tests because a payor's members today may not be their members when the benefits are realized

# Analysts' Estimates Are Likely Wildly Optimistic, Resulting in a Wildly Overvalued Stock

- Stock price (9/20/14 close): \$23.86
- Market cap: \$1.98 billion
- Cash: \$235 million
- Debt: \$1 million
- Enterprise value: \$1.74 billion
- 2014 est. EPS: -\$1.19-1.29
- 2015 est. EPS: -\$1.07-1.40
- 2016 est. EPS: \$0.12
- 2017 est. EPS: \$0.87
- 2015 est. revenue: \$76-121 million
- 2016 est. revenue: \$175-265 million
- 2017 est. revenue: \$330-418 million



Even if the company achieves \$418 million in revenues in 2017, analysts are valuing EXAS today at more than *four times* this amount!

# How I Think It Will Play Out

- We've seen this story before: Cologuard is Exact Sciences' third attempt at a stool DNA-based diagnostic – and the first two (PreGen Plus and ColoSure) were total busts, never obtaining over \$250,000/quarter in sales (the best quarterly sales, in Q4 2004, were a mere ~700 diagnostic tests)
  - The earlier tests were laboratory-developed tests and thus didn't go through the Premarket Approval/FDA approval process that Cologuard did, but the earlier tests were known and simply not used
- One analyst (Jefferies) is projecting 215,000 tests in 2015, 500,000 tests in 2016 and 800,000 tests in 2017
  - I'd be shocked if the company achieves even half of this amount
- By early 2015, it should be clear that adoption of Cologuard will be slow and the stock will get hit hard

# I Think This Will Meet the Same Fate as the Amazon Fire Phone

- A hugely hyped product entering a crowded market with high expectations – and is a total bust
- This was the lead story in the business section of the NY Times:

## *Amazon Cuts Struggling Phone's Price to 99 Cents*

By DAVID STREITFELD SEPT. 8, 2014

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SAN FRANCISCO — Sixty thousand people [vied to attend](#) the unveiling of [Amazon's](#) first smartphone in late June.

If only the retailer could persuade those fans — or anyone, really — to actually buy the device. The Amazon Fire is threatening to become the Amazon Fizzle.

On Monday, Amazon took a drastic step to avert disaster, announcing that it would charge 99 cents for the phone, basically giving it away if users signed a two-year contract with AT&T, the exclusive carrier.



Jeffrey P. Bezos, Amazon's founder and chief executive, announcing the Fire phone in June. Ted S. Warren/Associated Press



# My (Generous) Price Target Is \$8

- In its report assigning EXAS a “Sell” rating, Maxim Group writes:  
**Valuation is expensive.** Shares of EXAS trade at EV/revenue multiples of 6.8x and 5.3x our 2017 and 2018 revenue outlooks, respectively, compared to peer 2014 and 2015 averages of 4.6x and 4.1x. Our 12-month target price of \$8 is based on EXAS trading at a EV/revenue multiple of 3.5x our 2018 revenue outlook and discounted back to 2015. We believe that, in 2018, the company should trade at a discount to the peer average, given our view that blood-based screening tests are a significant competitive threat.
- I think this is generous: my best guess is that, as Cologuard fails in the marketplace, the stock falls 50% in the next six months (\$12) and 80% in the next year (<\$5)

# Summary: There Are Many Ways to Win

- The valuation is extreme – a nearly \$2 billion market cap for a single diagnostic product company
- Patients reject Cologuard’s “poop-in-a-bucket” system
- Physicians resist switching away from a FIT test they know and trust, especially given Cologuard’s high cost and false positive rate
- Competition emerges
- Commercial payor adoption is slower than anticipated

The best time to short overhyped, pie-in-the-sky, dream stocks is when all the good news is out and they have to prove themselves in the marketplace