

**December 19, 2012** 

### Has the Halo Been Broken on Intuitive Surgical?

# While Wall Street Sleeps, Citron Notes This Wall Street Darling has Passed the Tipping Point

Citron believes \$350 is coming .... "for now". 18-month target: \$250.



#### Overview

Citron examines a company desperately trying to keep up its "market darling" reputation on Wall Street.

But the high earnings multiple conferred on Intuitive Surgical (NASDAQ:ISRG) does not align with:

- a track record of excessive and unjustified marketing claims
- the utter lack of clinical evidence of superior medical outcomes when using its product for surgery, and
- the gathering storm of legal liability accruing to the company due to its failure to adequately disclose risks prior to its technology causing adverse surgical outcomes, scattered among the hundreds of thousands of surgeries performed with its robotic surgery devices.

Over the past few months, Citron has been compiling information about the marketing practices of Intuitive Surgical, **but just within the past month**, a number of new and decisive data points have emerged that Wall Street has not noted, which we thought justified calling out immediately. This is not the first time Citron has written on a medical technology company or a medical company whose revenues are materially dependent on insurance companies' reimbursement procedures and policies.

#### **Context: Citron's Health Care Industry Reporting**

Over the years, Citron has been the first to identify serious problems for investors in several medical technology and pharma companies, including:

Ticker / Company / Investor losses	Segment	Date First Reported/ Stock Price	Issues	Outcome
ARTC Arthrocare > - 90% loss	Joint/spine arthroscopic surgery	4/18/2008 \$55 per share	Inflating revenues and margins by manipulating coding system, running insurance scam	Restated 7 years of earnings; management resignations, stock fell to \$3, recovered to \$33 years later with new management
AMED Amedisys > 80% loss VVUS Vivus > 65% loss	Home health and hospice care Weight loss drug	8/12/2008 \$60 per share 7/19/2012 \$30 per share	Systematic manipulation of medical coding for reimbursements  Overhyped drug; manage- ment bad track record of; lack of competitive advantage; reimbursement challenges	Congressional and DoJ Investigations, lawsuits, tighter regulations. Stock is now \$12 Disappointing drug rollout; insurance reimbursement struggles; stock is now \$13 per share
QCOR Questcor > 50% loss	High-priced drug for rare conditions	7/10/2012 Stock \$55 per share	Increasing scrutiny re Insurance reimbursement; low cost drug alternatives	Stock hit low of \$19, now \$29.

(NOTE: All of these stories are posted in CitronResearch.com archives.)

What two circumstances do these businesses all have in common?

- 1) All four of these stocks fell by 50% to 90% since the date Citron first identified the critical structural problems in their business models. In each case, the point was not the knee-jerk response of the stock in the minutes, hours or days following publication, it was the investment thesis being proven right in the course of time.
- 2) Each of these companies is dependent upon a business model which relies on distorting the medical coding and insurance reimbursement system to earn the preponderance of its revenues or generate its growth.

Inuitive Surgical (ISRG) is unique because the da Vinci is a product that has not been sold to meet patient need, as most medical devices are, but rather it has been sold using fear to hospital management purchasing committees. Aggressive salespeople have escalated a "medical arms race" into high technology, regardless of whether surgeries with this device produce significant medical benefit or not.

### Medicine for profit over utility is not an uncommon theme, but now the lawyers have taken notice – and investors should take note as well.

It is Citron's opinion that Intuitive Surgical has reached exactly this tipping point. Not a tipping point which will put the company out of business, but rather a tipping point that could break the halo and have Wall Street assign a comparable multiple to other mainstream medical device companies... that could take this stock down 50%.

Here are the new data points of the last four weeks:

- Three new highly credible lawsuits over hysterectomies with bad outcomes have been filed in addition to six really ominous ones from earlier in the year
- Large insider sales. Within the last month, Chairman Lonnie Smith sold shares from options exercise (not 10(5)b) <u>netting over \$50 million</u>, a rather large percentage of his recently apportioned stake
- Peer criticism a number of recent articles summarizing from highly credible, recent studies that highlight the gap between the company marketing materials' claims and full scientific disclosure of the true risks and differentials in medical outcomes. This gap creates the basis for legal challenges to the company due to inadequate disclosure of the risks of bad outcomes.
- Further skepticism about the true cost/benefit of robotic surgeries
- Indications of loss of morale and sharp erosion of confidence in management and oversaturation coming through the sales force

But the most serious issue facing Intuitive is that while its deployment is well past the 10 year point into mainstream healthcare in the US, there is still a **severe vacuum of real scientific evidence that the da Vinci is of any clinical benefit when the full arc of costs and outcomes are weighed**, in the most commonly performed surgeries in which it is utilized. While this is not a new thought, the current legal cases will bring this issue to the forefront.



### **Background**

Intuitive Surgical, (NASDAQ:ISRG) is the market leader in robotic-controlled surgery devices. The company sports a **\$22 billion market cap** with 99% of the stock in the float. It manufactures a very futuristic technology, a so-called robotic surgery system. The da Vinci is a \$1.5 - \$2.5 million-dollar machine that allows a surgeon to operate on a patient from a control console, manipulating a suite of tiny computer-assisted remote control tools through a small tube inside a patient, reproducing tiny and precise movements with tools at the surgical site which could not be performed otherwise.

The apparent advantages of such types of surgery were really easy for patients and investors alike to comprehend: much smaller incisions, the presumption of faster and less painful healing from surgery, and shorter hospital stays. Intuitive enjoyed strategic first

mover advantage in the US, and for several years the company's sales force made persuasive headway with the nation's hospitals, convincing their purchasing committees to commit to purchasing these expensive machines, because they would be absolutely necessary to compete in the modern age of medicine.

Intuitive's sales team was able to convince many hospital purchasing committees that they needed this technology to "compete" for patients. Sales soared, and with them, expectations of a growing number of new procedures would increase revenues of the razor-blade model for single-use kits, wider training of surgeons in its use, and an ever expanding market to capitalize on its first-mover advantage. This has all worked out happily for investors, with Intuitive's stock growing 20 fold over levels a decade ago.

Superficially, the da Vinci offers so much of the 'wow factor' it is all too easy for business judgment to wilt before visions of surgical robots as pure medical magic, inspiring investors to leap to the conclusion that da Vinci is the future of all surgery, and lose focus on the nuts and bolts of basic business discipline. In doing this, the market has looked past the glaring vulnerabilities of Intuitive Surgical's business model.

For Intuitive, growing its business is a complex process; not only does it face a long sales cycle for the most expensive single piece of equipment in a typical hospital's surgery suite, but each type of surgery the equipment is used on is really a separate market: it requires its own specialized tools to attach to the robot, separate FDA approvals for the entire procedure plus the attachments, and specific training for the surgeons already expert in performing it without the robot. And only then does the monetization challenge kick in: how to code the procedures so medical insurance companies will reimburse the higher costs, especially without new reimbursement codes, which would require scientific justification of the higher cost procedure.

So far, it has breeched just two high-volume surgeries which comprise the vast majority of procedures it is used for: prostate surgeries and hysterectomies (over 31% and 40% of da Vinci procedures in 2011, respectively). Ironically, the latter is an extremely common and not difficult laparoscopic surgery with non-robotic tools. The safety concerns now appearing in civil lawsuits cause a reasonable question as to whether the da Vinci is all too often, a solution looking for a problem.

Meanwhile sixteen analysts cover Intuitive Surgical. They all have neat little spreadsheets multiplying last quarter's numbers by their carefully calculated growth trajectory rates to calculate next quarter's "profit model", etc. But their models seem unable to detect the real storm clouds gathering for the company.



### The Documents the Company Doesn't Want You to See

(One patient's intestines were hanging out of her vagina; another was uncontrollably passing urine out of her vagina, while two "routine" hysterectomies resulted in death of the patient, with apparent damage caused by the da Vinci device)

Hysterectomies are now da Vinci's single highest volume application. But within the last month, three new separate lawsuits have been filed on behalf of defendants upon whom gynecological surgery was performed, with disastrous results. This is on top of six others filed earlier in 2012. Here are the major similarities in numerous cases filed so far:

- Filed in 2012
- Hysterectomy/Gynecology bad outcomes (One was a heart valve procedure)
- Long-lasting medical consequences
- Filed by credible attorneys, not by class-action-troll firms
- Surgeons in these cases **are not** named defendants
- Product marketing claims of Intuitive Surgical cited as misleading in every case
- Intuitive Surgical accused of failure to disclose accurately the risks of use of its device
- Excessive, deceptive and manipulative marketing practices a foundation of damage claims
- Burns resulting from unintended electrical discharge; damaged insulation and/or
- Unintended tissue damage, tears and other tissue impacts



# Selected 2012 Civil Lawsuits against Intuitive Surgical

Plaintiff	Attorney	Venue	Date Filed	Details
<u>Cook</u>	Audet	US District,	12/14/2012	Injury as a result of
		Northern		hysterectomy
7 anials	Comagas	California	12/12/12	Injury of a regult of
<u>Zarick</u>	Geragos	Superior Court, State of	12/12/12	Injury as a result of hysterectomy, intestines
		California		rupture through vagina
Lerhaupt	Hersh	US District,	11/21/2012	Injury as a result of
<del>2011aapt</del>	Burton	Northern	11/21/2012	hysterectomy and gall bladder
		California		removal
Chronister	Bannasch	Circuit Court	8/1/2012	Injury during hysterectomy
		of Orange Co,		caused death
		Fla	_ (2 - (2 - (2 - (2 - (2 - (2 - (2 - (2	
<u>Rister</u>	Becnel	US District,	7/25/2012	Injury as a result of
	Hersh	Northern		hysterectomy
Kucharczyk	Burton Becnel	California	7/18/2012	Heart walve gurgery, rehetic
Kucharczyk	Hersh	US District, Northern	//10/2012	Heart valve surgery, robotic arms "jolt" with too much
	Burton	California		pressure, puncture patient's
	Durton	Camorma		liver and spleen
Salisbury	Oliver	US District,	7/6/2012	Hysterectomy; broken
		Eastern	, ,	instrument part lodged in
		Michigan		patient, causing further injury
		Southern Div		during retrieval
<u>Mayfield</u>	Penton	US District	5/7/2012	Injury as a result of
	Becnel	Court,		hysterectomy
	Riley &	Southern Miss		
Ionos	Jackson Blaudeau	US District	4/10/2012	Hystorostomy sausad injury to
<u>Jones</u>	Diaudead	Court,	4/10/2012	Hysterectomy caused injury to left ureter and bladder.
		Northern		"Involuntary loss of urine
		District of		through vagina"
		Alabama		- 0 0 -
<u>McCalla</u>	Rheingold	US District	4/4/2012	Hysterectomy burned artery,
		Court,		caused death
		Southern Dist		
		NY		



### The Most Disturbing Lawsuit Ever:

# "Prostatectomy Patient Who Urinated Out of His Rectum and Defecated Out of His Penis Suing Robot Maker"

"The surgeon, Christopher Kopp, MD, said in his operative report that the robot malfunctioned several times. When he and the technicians couldn't get it working properly, he decided to convert to an open procedure."

Outpatient Surgery, February 2011

hhttp://www.outpatientsurgery.net/news/2011/02/21-prostatectomy-patient-who-urinated-out-of-his-rectum-and-defecated-out-of-his-penis-suing-robot-maker

These patients all required debilitating and painful subsequent surgeries to repair defects caused by the original robotic surgery, and aside from the two patients who died, the remaining patients were left with severe long term adverse results. How do patients suffer burns from da Vinci? See this photo.



Fig. 1. Cracked plastic sheath after a long surgical case, which led to insulation failure.

Cormier, Electrocautery Injury in Robotic Surgery, Obstet Gynecol 2012. Investors need to be aware that these cases are different than many cases in the past. First, the company is the sole named defendant in these cases, not a co-defendant with the doctor. With three new lawsuits filed in just the last month, attorneys are starting to focus culpability on the device maker rather than the doctor. This shift in legal responsibility differs from the pattern of asserted liability over past years. Secondly, the language in many of these suits is identical -- thereby suggesting strongly to Citron that a major class action case led by one of these attorneys is in the offing.

In particular, one of the suits, filed last week in California court, is being prosecuted by Mark Geragos, a high profile California litigator who we are sure will not be shy in stirring up plenty of publicity about the matter. Another three cases filed this year are filed by "tort king" Daniel Becnel – read about him here:

http://www.businessweek.com/magazine/content/10 23/b4181066654108.htm

These two gentlemen will make full use of the discovery phase of their lawsuits to expose all of the secrets behind the aggressive and inappropriate marketing methods used by Intuitive Surgical. Look how industry publications describe company marketing materials and photos being displayed widely on hospital websites to tout da Vinci surgeries, rather than clinical data studying outcomes, to induce patients to seek out robotic surgery.



## **Consequences of Litigation Risk**

A future potential negative catalyst for Intuitive Surgical could soon emerge in a requirement that patients sign a letter of informed consent before receiving robotic assisted surgery. Whether it be the hospitals, lawyers, doctors, or insurance companies -- the risks have become too great for patients not to be informed. Every lawsuit that gets filed brings us one step closer to this necessary patient informed consent to be implemented.

Patients must be informed about the true risks /benefits, and more importantly the skill level of the attending surgeon, when undergoing surgery using da Vinci machines. <a href="http://legal-dictionary.thefreedictionary.com/Informed+Consent">http://legal-dictionary.thefreedictionary.com/Informed+Consent</a>

The overall impacts upon utilization rates for da Vinci machines is difficult to predict, but it is Citron's opinion that the days of hospitals "competing" for patients by touting robotic surgery are rapidly coming to a close.

Instead of boring you with article after article, Citron excerpts the most relevant quotes of noted experts and medical journals in their respective fields, about this cluster of issues:



## **Review of Robotic Surgery Marketing on Hospital Websites**

From the American Journal of Obstetrics & Gynecology, Sept 2012

Conclusion: "Marketing of robotic gynecologic surgery is widespread. Much of the content is not based on high-quality data, fails to present alternative procedures, and relies on stock text and images."

Schiavone MB, Kuo EC, Naumann RW et al.

The Commercialization of Robotic Surgery:
Unsubstantiated Marketing of Gynecologic Surgery by Hospitals
American Journal of Obstetrics & Gynecology
Volume 207, Issue 3, Pages 174.e1-174.e7, September 2012

http://download.journals.elsevierhealth.com/pdfs/journals/0002-9378/PIIS0002937812006643.pdl

"Although most patients trust the health information provided by hospitals, this study indicates that much of the Web-based information on robotic gynecologic surgery is not backed by sound evidence and is influenced by the manufacturer. This approach to promoting the robot drives up the cost of health care and misleads patients.

--Andrew M. Kaunitz, MD

Professor and Associate Chairman, Department of Obstetrics and Gynecology

University of Florida College of Medicine – Jacksonville

OBG Management Board of Editors

**OBG Management Article** 

"Johns Hopkins research shows hospital websites use industry-provided content and overstate claims of robotic success"

http://www.hopkinsmedicine.org/news/media/releases/hospitals\_misleading\_patients\_about\_benefits\_of\_ robotic\_surgery\_study\_suggests

Johns Hopkins Medicine, 5/18/2011

Citron is amazed that it has taken so long for the legal community to catch up to the medical community. It is totally inexplicable that, despite the intense marketing hype generated by a company with a \$2 billion revenue run rate, there is **still <u>no clinical</u>** <u>evidence</u> of better medical outcomes for surgeries performed with its devices.

"Out of all the instruments and surgical tools that hospitals have adopted, this is one of the most expensive items in American operating rooms today,"

"It's a symbol of what's wrong with American health care: the widespread adoption of expensive new technology with little evidence to support its use — all within the context of a poorly informed, even misinformed, public."

-- Dr. Marty Makary

General Surgeon, Director of Surgical Quality Author of a Study of 400 Hospital Websites Making Scientifically Unsupported Claims about Robot-Assisted Surgery

http://articles.chicagotribune.com/2012-02-25/news/ct-met-robot-20120225\_1\_robot-assisted-intuitive-surgical-prostate-removal-surgeries

#### [ With regard to prostate surgeries...]

"But for the big three outcomes—cancer control, urinary control, and sexual function — there is still no clear answer as to whether one approach is superior to another"

-- Dr. William Lowrance
Urologic Oncologist
Huntsman Cancer Institute, University of Utah
http://www.cancer.gov/ncicancerbulletin/080911/page4



# Benefits Often Not Supported by the Science

Beyond the lawsuits, data is piling up that robotic hysterectomies are yielding outcomes no better than conventional laparoscopic surgeries, yet with consistently higher costs.

#### From the Journal of Minimally Invasive Gynecology

"Our findings reveal little clinical differences in perioperative and postoperative events. This, coupled with the increased per-case hospital cost of the robot, suggests that further investigation is warranted when considering this technology for routine laparoscopic hysterectomies."

Comparing Robot-Assisted with Conventional Laparoscopic Hysterectomy

# Lack of Training Standards for Doctors, and No Accountability for "Splashy" Ads, Often Not Supported by the Science

#### From the Seattle Times July 2012:

"Today, 12 years after the FDA first approved the da Vinci, there is still no industry standard for training and credentialing of doctors to use the robot, beyond a basic course by the manufacturer."

"And some surgeons and hospital officials say it's being overused, employed for procedures where it offers no advantage."

"Splashy ads by hospitals claiming better outcomes and shorter stays appeal directly to patients, despite conflicting studies on outcomes and complications, depending on the procedure."

http://seattletimes.com/html/localnews/2018631542 robot08m.htm

# Training a Primary Impact on Outcomes in Prostatectomies, <u>Not</u> the Type of Surgery Chosen

"Furthermore, rates of blood loss, positive surgical margins, incontinence, and erectile dysfunction vary widely from surgeon to surgeon. 13 It has become clear that the best chance for cure rests in the most experienced hands in patients in all risk groups" -- Open vs Laparscopic Vs Robot-Assisted Laparoscopic Prostatectomy:

The European and US Experience Reviews in Urology

http://www.ncbi.nlm.nih.gov/omc/articles/PMC2859140/?tool=pmcentrez

Finkelstein, Eckersberger, Sadri, Saneja, Lepor and Djavan

One Hospital's experience: Significant Injuries caused by robotic surgeries. -- From the Wall Street Journal: May 2010

"At Wentworth-Douglass, however, the robot has been used in several surgeries where injuries occurred. One patient operated on days after the hockey game was so badly injured that she required four more procedures to repair the damage. In earlier robotic surgeries, two patients suffered lacerated bladders."

http://online.wsi.com/article/SB10001424052702304703104575173952145907526.htm

American College of Obstetrics and Gynecology calls for more data to determine the role of robotic surgical machines performance.

"The American College of Obstetricians and Gynecologists has been firmly opposed to the robot for the potential hazards it presents to patients."

http://www.reuters.com/article/2012/11/01/idUS215464+01-Nov-2012+PRN20121101

Driving up Health Care Costs without Commensurate Benefits - Kaiser Health Care

From a Kaiser Health Care Newsletter / Blog:

"But after researchers studied thousands of robotic surgeries, it turns out that, but for a few exceptions, surgery outcomes aren't any better and patient's recovery time actually aren't any shorter."

http://capsules.kaiserhealthnews.org/index.php/2012/03/why-are-health-costs-so-high-the-robotknows/?referrer=search

#### "In Medicine, Falling for Fake Innovation" - New York Times

"The critics are right — if they're talking about innovations like the da Vinci robot, which costs more than a million dollars and yet has never been shown by a randomized trial to improve the outcomes of prostate surgery. Indeed, a 2009 study showed that while patients had shorter hospital stays and fewer surgical complications like blood loss when they underwent this kind of robotic surgery, they later "experienced more ... incontinence and erectile dysfunction".

--Ezekiel J. Emanuel Oncologist and former White House adviser, is a vice provost and professor at the University of Pennsylvania.

http://opinionator.blogs.nytimes.com/2012/05/27/in-medicine-falling-for-fake-innovation,

# Intuitive Surgical got their prostate checked -- and the results were not encouraging.

The company's two highest-volume procedures are by far prostate surgeries and hysterectomies (over 31% and 40% of da Vinci procedures in 2011, respectively). Let's look at the factors in play with these primary uses of da Vinci.

The first sign of real operational results problems surfaced in the last quarter when use of Intuitive's equipment for prostate surgeries suddenly and unexpectedly lost its sharp uptrend. Interestingly, the problem is not competitors, but rather competing with "doing nothing". Studies, most specifically, an article in the New England Journal of Medicine, (<a href="http://www.nejm.org/doi/full/10.1056/NEJMoa1113162">http://www.nejm.org/doi/full/10.1056/NEJMoa1113162</a>) now conclude that for many prostate cancers, the surgical outcomes are little to no better statistically than **no treatment at all**. These studies were of immediate impact in terms of decrease in use of da Vinci.

All other things being equal, this quarter's decline in prostate procedures would have been devastating for investors. After all, prostate surgery was really the flagship condition that drove da Vinci sales for years. But the company stated that **other procedures (of which the vast majority would be hysterectomies)** made up the difference in revenues and profits. And we know what the result of pushing hysterectomies down the food chain will be: more marginal cases, more marginally trained doctors, and an increased percentage of damaged outcomes.

"Conclusion: Risks of problems with continence and sexual function are high after both procedures. Medicare-age men should not expect fewer adverse effects following robotic prostatectomy".

Journal of Clinical Oncology

Adverse Effects of Robotic-Assisted Laparoscopic Versus Open Retropubic Radical Prostatectomy Among a Nationwide Random Sample of Medicare-Age Men Barry, Gallagher, Skinner and Fowler

http://jco.ascopubs.org/content/early/2012/01/03/JCO.2011.36.8621.abstract



## Dissention in the Ranks:

The stresses of maintaining a high growth company while fighting insurance companies and medicine are evident on the popular employee message board CafePharma, which is a must read for everyone in pharmaceutical and medical device world.

After reading this board, Citron is of the opinion that the sentiment of the employees is a canary in the mine for a company with an oversaturated sales channel.

"Expect 2 to 3 calls per day (yes day) asking you about your number and how many cases you are bringing in. If a surgeon takes vacation or doesn't schedule 3 hysterectomies in his/her block or if a case gets cancelled you better have a good explanation for it."

"Wow. Started with the company 3 years ago and this post is dead on accurate."

"I am training a doc now who did 18 hysterectomies last year because I'm doing everything and anything to try and hit my unrealistic number set by my CSM and CSD."

"I, too, have never posted. I agree with everything above. Micromanage IS the culture....and recently I was "forced" out. Forced out due to reasons the above and that I would not lower my standards to talk to my docs into using the da Vinci for reasons that did not involve patient benefit."

"I had the exact same experience while at Intuitive. I will never be able to fully explain why so many good people are pushed out???"

"This one certainly caught my eye, and most of the information here is accurate. The company is not what it was 3 to 4 years ago, Intuitive has become a company motivated by greed and the posts about the management team's fear culture is the truth. Reps today have an average of 3 accounts to cover without enough to do, so we baby sit cases with surgeons who don't need us there. I get asked every day "why are you hear I've done over 200 cases" The OR staff is sick of seeing us hanging around the OR all day and for the most part we are taking up space watching cases. Surgeons we have left to train are the bottom of the barrel with minimal surgical skill,

but we are left to train to "hit the buckets." "

"I heard that Steve Kroft of 60 minutes is trying to produce a special investigative report story on Intuitive. It was going to highlight the company's technology & the business tactics it uses against hospitals and employees to maintain growth.

Does anybody have any insight to this?"

"I heard that there are some disgruntled Dr's that are not happy with the stiff arming that Intuitive tries to pull when trying to convert easy lap cases over to da Vinci."

"any sense of when this will be aired? It looks like there have been a lot of MAUDE issues lately"

The posts are recent, consistent in perspective, and nobody is refuting them.

http://www.cafepharma.com/boards/showthread.php?t=517832 http://www.cafepharma.com/boards/showthread.php?t=505121



#### **Future Reporting**

There are a number of topics of ongoing investigatory work that Citron will provide updates on in coming weeks. Among the interesting questions:

- 1) What are reasonable estimates of reserves the company should be accruing against the estimated impacts of future litigation losses, and the impacts on company revenue projections?
- 2) If the hysterectomy litigation goes to class-action status, what are the impacts for the company's profits?
- 3) Exactly how does da Vinci surgery manage to get insurance reimbursement at higher rates than standard laparoscopic surgery? Is this cost increment sustainable? Will insurance companies continue to tolerate this higher rate of reimbursement structure without convincing clinical evidence of superior outcomes to justify the costs?
- 4) What are the impacts of Obamacare on company revenues?
- 5) What is the FDA's MAUDE and why should investors care about it, even though it's never been mentioned in a SEC filing or a conference call?
- 6) Are there signs of under-utilization of da Vinci systems already purchased and installed in hospitals? What does this say for the sustainability of Intuitive Surgical's future revenues?
- 7) What level of training is really required to develop reliable levels of competence using da Vinci? Why are there no real licensing standards? We've seen doctors opine that it takes 300 surgeries to really feel confident in this modality. Who will be the patients for all those in-training surgeries? As the force for new sales drives more and more marginal surgeons into the pipeline, does the level of expertise decline? Does the rate of bad outcomes rise?
- 8) Are da Vinci's procedure counts being skewed, in light of sales commission policy to cast a blind eye on consumables being reported by the sales force as used on higher-commission surgeries (other than hysterectomies)?



Meanwhile, Intuitive still enjoys "darling status": a market cap that is 10x revenues, forward EPS over 30x, and a crowd of analysts drawing sloping lines upward to the sky. Citron is sure that every analyst who hears about this piece will be out with a note defending this stock before they even read the work, which is (18 pages, plus over 20 links). That seems to be standard practice for the sell side. In our 12 years of reporting with unparalleled accuracy, we have NEVER seen an analyst back away from a medical company we reported until after it is too late ... and shareholders lose money: Viva Wall Street! For those who say that some of this report is old news we suggest you rethink. Is this a scenario that occurred years ago, simply part of the company's past history, or are these data points that are only going to get worse, as the insatiable thirst for growth drives the company to push more novice surgeons to perform unnecessary robotic surgeries, with potentially dangerous outcomes?

If this is the case, then this story is foretelling the future by understanding the past ... - **NOW THAT IS ANALYSIS!** 



#### **Conclusion**

Circumstances are converging on Intuitive Surgical, and it is Citron's opinion that the stock is ripe for its own bad outcome – for investors. The company achieved tremendous initial commercial success by selling its high-tech machinery into the surgical suites of the nation's hospitals. But the primary motivation was marketing – the hospitals' fears that robot surgery would be demanded as the standard of care by patients when selecting medical care providers.

Now several years have passed, with prostate surgery and hysterectomies being the breadand-butter of mainstream utilization da Vinci procedures. All we know from all those outcomes is that they definitely cost the health care system more. This cost was borne by insurance companies and passed on to all of us. There is marginal data showing shorter hospital stays and less invasive surgical sites for the hysterectomies, but overall medical outcomes are no better. And for prostate surgery, no treatment is looking competitive to any surgery at all with regard to outcomes.

Citron is sure that in the hands of a really skilled surgeon, da Vinci can produce some favorable outcomes. But the numbers don't show a decisive advantage, and the costs of litigating and compensating the victims of really bad outcomes hasn't even been factored in yet – those costs are uncovered later, and are just now beginning to surface.

Downward vectors that should be considered by all investors are:

- Reversion of this stock to realistic multiples for the top medical device companies
- Reducing estimates to allow for the establishment of realistic legal loss reserves for the liability exposure for deceptive marketing, and patient injuries and damages
- Reduction of estimates to account for the "saturation factor" in hysterectomies and the declining market for prostate surgery

It is Citron's opinion that, considering all the facts as outlined above, one third to one half of Intuitive's Surgical's stock price could be excised. For investors, that would be an operation without anesthetic.

**Cautious Investing to All**