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AtriCure (ATRC): 57% Downside on a Maze of Highly Paid Doctors, Off-Label Device Usage, and Ongoing DOJ Investigation

AtriCure, Inc. ("the Company") develops and sells devices for the surgical ablation of cardiac tissue. The Company's devices are used in (1) Open-Heart concomitant procedures (est. 65% of revenues) and (2) standalone "minimally invasive" procedures (est. 35% of revenues). The Company claims its mission is "passionately focused on reducing the global Afib [atrial fibrillation] epidemic and healing the lives of those affected." In reality, we believe AtriCure is complicit in the proliferation of unnecessary and unsafe surgeries administered by highly conflicted physicians.

As open-heart procedures (such as CABG, MVR, and AVR) are being rapidly displaced by less-invasive procedures, the Company's Open segment is under structural pressure. Thus, AtriCure has sought to replicate its Open procedures in a standalone, minimally invasive setting. The Company has run four studies thus far to prove out safety and efficacy. However, these procedures remain off-label; per the Company, "We do not currently have any products with FDA approved indications for the standalone treatment of Afib." Nevertheless, MAUDE adverse events indicate that over appx. the past 3 years, 24 patients have died in AtriCure's "minimally invasive" standalone procedures, of 32 deaths in total. We consulted with a widely published and renowned cardiologist on each of these cases, who concluded that "These are far worse than I had imagined ... Most are directly related to the procedure, which makes me quite nervous. Certainly, I would be very, very hesitant to recommend this to any of my patients and any doc looking at these would feel the same way."

These facts are concerning on their own, but especially so as we believe that the Company has partnered with a group of prescribing physicians that engage in direct-to-patient marketing of these "minimally invasive" procedures, hence subverting potentially safer, more effective, cheaper, and faster lines of treatment. While the Company portrays itself as disengaged from the actions of its prescribing surgeons, it has simultaneously paid out $19.8 million to physicians from 2013 to 2018, a shocking figure at 6x to 7x peer levels. On page 10, we introduce readers to 5 of AtriCure's highly paid physicians, "The Starting 5." Among them, we found allegations of a wrongful death via a "needlessly extensive, maverick, and unconventional" surgery, amidst other malpractice; off-label marketing of surgical ablation procedures; failure to disclose financial relationships; and undisclosed marketing relationships. Moreover, we believe physicians unnecessarily lengthen patient treatment schedules so as to effectively double-bill for these two-part "staged" procedures, hence earning immense profits on each procedure.

The DOJ is already investigating AtriCure and has issued a Civil Investigative Demand related to "the promotion of certain medical devices related to the treatment of atrial fibrillation for off-label use and … false claims to certain federal and state health care programs for medically unnecessary healthcare services related to the treatment of Afib." We believe the same practices that have been at the heart of its minimally invasive segment and related appendage management devices (the Company cites 100% AtriClip penetration in DEEP and 50% in Convergent procedures) are likely under the scope of this investigation, the resolution of which ought to impair this business.

Additional red flags include bizarre circumstances surrounding the original Synergy Ablation System PMA approval (long-term results remain pending); litigation against AtriCure's Chinese distributor, who allegedly never penetrated the market, but rather stole the Company's IP; and a history of value destruction from CEO Michael Carrel, who previously ran a dot-com era CRM software business. The Company has serially disappointed on guiding analysts to eventual EBITDA profitability, and is now guiding to a loss of somewhat less than $10 million in 2020. Our valuation of $11.32 per share is generously based on a 12x multiple on $64 million of 2023 EBITDA (implying 20% margins). We believe that many AtriCure investors have misplaced long-term hope in the Company's "minimally invasive" surgical business, and shares ought to reach intrinsic value as the DOJ investigation is resolved and investors realize the true drivers of AtriCure's "success".

AtriCure's "Minimally Invasive" Surgeries

AtriCure develops and sells devices for the surgical ablation of cardiac tissue, or the scarring of the heart, the primary purpose of which is to treat atrial fibrillation (Afib). AtriCure breaks its product offering into three segments: Open Ablation (46% of LTM revenues), MIS Ablation (20% of LTM revenues), and Appendage Management (34% of LTM revenues):

Open Ablation and MIS Ablation devices are used in concomitant open heart and in standalone "minimally invasive" surgeries, respectively, while Appendage Management tools (the AtriClip) are used across both types. Per management comments and the split of the rest of the business, we assume that Appendage Management segment revenues are tied 50% to Open and 50% to MIS procedures, resulting in 65% of revenues generated from open-heart procedures and 35% of revenues generated from "minimally invasive" surgical procedures.

We refrain from providing pictures in this report, but curious readers can find that these so called "minimally invasive" procedures involve the creation of multiple "working port" incisions on each side of the chest/abdomen, each up to 5.0cm in length, in addition to "observation port" incisions of ~1.0cm in length. Thus, these surgeries are far more dangerous than concomitant/open procedures, as the concomitant procedure adds little incremental risk once the chest is already cracked. AtriCure has already conducted 4 studies over the past several years that attempted to transition the concomitant procedures to standalone settings in a safe and effective manner. We believe the results confirm our view that standalone surgery remains relatively dangerous and ineffective:

AtriCure Minimally-Invasive Surgical Ablation Studies								
Start Date	End Date	Study Name	NCT	Device(s)	Enrollment	Efficacy	Adverse Event Rate	Notes
May-07	Jan-13	FAST	NCT00662701	Bipolar Synergy Ablation System	120	67.2%	34.4%	Flawed study design put CA at disadvantage vs. SA
Nov-10	Nov-13	DEEP AF	NCT01246466	Bipolar Synergy Ablation System	24	N/A	29.2%	Study was halted early; only 7 patients had 6-month data
Aug-12	Dec-15	Staged DEEP	NCT01661205	Bipolar Synergy Ablation System	30	78.3%	24.0%	Two parts of procedure staged 1 to 10 days apart
Sep-15	Mar-18	HT2AF	NCT02630914	Bipolar Synergy Ablation System	12	???	???	No results available; typically a bad sign

Note that each of the above studies used the Synergy Ablation System, which we believe the Company had been relying on to test well in standalone trials. However, a poor outlook led the Company to acquire nContact in October 2015, which brought the Epi-Sense system and the CONVERGE trial in recruitment. The Company now focuses its efforts here (and in DEEP Pivotal) and will present CONVERGE results to the FDA in the first half of 2020. AtriCure's investor presentation notes that the "Evolution to minimally invasive therapies will drive growth" and "core business is evolving to serve the MIS market and capture more of long-term growth opportunity."

However, given the Company still lacks FDA approvals, AtriCure's standalone "minimally invasive" surgical procedures for the treatment of Afib remain entirely off-label. Nevertheless, the MAUDE adverse event database indicates that over roughly the past 3 years, there have been 32 deaths and 154 injuries associated with AtriCure's devices. Recurring complications include stroke, bleeding complications, atrio-esophageal fistula, and diaphragmatic / incisional hernias. **Of these 32 deaths, a remarkable 24 of them occurred in "minimally invasive" (i.e. hybrid / convergent) procedures, most often using Epi-Sense:**

Report Number	Event Date	Report Date	Adverse Event	Procedure Type	AtriCure Device
3011706110-2019-00026	4/15/19	5/14/19	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2019-00021	3/28/19	4/23/19	Death	MVR	ATRICURE ATRICLIP LAA EXCLUSION SYSTEM WITH PRELOADED G
3011706110-2019-00018		4/16/19	Death	AVR	ATRICLIP LAA EXCLUSION SYSTEM WITH PRELOADED GILLINOV-C
3011706110-2019-00016	3/6/19	4/3/19	Death	Convergent	ATRICLIP LAA EXCLUSION SYSTEM WITH PRELOADED GILLINOV-C
3011706110-2019-00012	2/19/19	3/20/19	Death	Maze	ISOLATOR TRANSPOLAR PEN
3011706110-2019-00010	1/24/19	2/21/19	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2019-00007	1/7/19	1/28/19	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2018-00218		11/13/18	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2018-00207	8/8/18	8/27/18	Death	Convergent	WOLF LUMITIP DISSECTOR
3011706110-2018-00196	7/21/18	8/14/18	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2018-00187	6/2/18	7/11/18	Death	Multiple	CRYOICE CRYO-ABLATION PROBE
3011706110-2018-00185	6/19/18	7/3/18	Death	CABG	COBRA FUSION 150 ABLATION SYSTEM
3011706110-2018-00180	5/29/18	7/2/18	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2018-00179	6/12/18	6/29/18	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2018-00137	2/19/18	3/14/18	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2018-00112	12/5/17	1/4/18	Death	Maze	ATRICURE BIPOLAR SYSTEM
3011706110-2018-00111	11/28/17	1/4/18	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2017-00107		12/13/17	Death	CABG	ATRICURE ATRICLIP LAA EXCLUSION SYSTEM WITH PRELOADED G
3011706110-2017-00104	11/10/17	12/12/17	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2017-00102		12/7/17	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2017-00094		10/30/17	Death	Convergent	MULTIFUNCTIONAL LINEAR PEN
3011706110-2017-00080	8/22/17	9/14/17	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX, MOD
3011706110-2017-00083	7/28/17	9/14/17	Death	Convergent	COOLRAIL LINEAR PEN
3011706110-2017-00078	2/27/17	8/31/17	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2017-00071		8/14/17	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3011706110-2017-00064	6/23/17	7/20/17	Death	CABG	ATRICURE CRYO MODULE SYSTEM
3011706110-2017-00041	3/28/17	4/26/17	Death	Convergent	NCONTACT CANNULA ACCESSORY
3003502395-2017-00027	10/31/16	2/24/17	Death	Convergent	COOLRAIL LINEAR PEN
3003502395-2016-00172	10/27/16	12/9/16	Death	Convergent	COOLRAIL LINEAR PEN
3003502395-2016-00147	10/3/16	10/31/16	Death	Convergent	COBRA FUSION 150 ABLATION SYSTEM
3003502395-2016-00129	9/6/16	10/7/16	Death	Convergent	EPI-SENSE GUIDED COAGULATION SYSTEM WITH VISITRAX
3003502395-2016-00115	6/9/16	9/15/16	Death	Convergent	EPISENSE

We provided a highly-respected cardiologist with the full event logs, including injuries, to better understand the severity of the complications. He provided comments on many of them, which we highlight in the table below:

Report Number	Cardiologist's Comment
3011706110-2019-00029	Another surgical complication ... This would not happen with catheter ablation.
3011706110-2019-00027	Another bad stroke; yikes
3011706110-2019-00020	Another peri procedure stroke
3011706110-2019-00016	Another bleeding complication which seemed quite significant
3011706110-2019-00012	Terrible outcome
3011706110-2019-00010	Direct consequence of surgical procedure
3011706110-2019-00008	Another complication of surgical approach
3011706110-2019-00007	Terrible outcome, direct result of procedure
3011706110-2019-00005	Another terrible periprocedural complication
3011706110-2018-00223	Another nasty surgical complication
3011706110-2018-00218	We have seen this [atrio-esophageal fistula] a few times now; this is from the catheter
3011706110-2018-00209	Another massive periprocedural stroke
3011706110-2018-00208	This is going to be a problem for this procedure since most patients will have had prior ablations …
3011706110-2018-00207	This makes bleeding risk much higher as noted here, and oh my god he died, horrible
3011706110-2018-00203	Another awful periprocedural complication
3011706110-2018-00196	Wow, terrible outcome [stroke] from procedural complication
3011706110-2017-00102	Devastating complication [atrio-esophageal fistula]; have seen this a few times already
3003502395-2016-00172	Yikes; surgical complication [resulting in stroke and death]
3003502395-2016-00164	[Diaphragmatic hernia] has occurred earlier as well
3003502395-2016-00157	Another incisional hernia, surprised to see it this common
3003502395-2016-00147	Terrible [death from stroke after DEEP procedure]
3003502395-2016-00115	This hernia business appears to be a recurrent theme; in this case with terrible consequences [death]

We also provide the surgeon's concluding comments:

> **The fact that most of the complications are procedure, not device related is actually pretty bad**; you can improve the device, but the procedure appears to be difficult and complication prone … Eye opening and I can see why you shared these with me. **These are far worse than I had imagined** ... Most are directly related to the procedure, which makes me quite nervous. **Certainly, I would be very very hesitant to recommend this to any of my patients and any doc looking at these would feel the same way.** And note that these were done by the highest volume performers.

These comments are jarring when considering that there are several lines of treatment that patients ought to consider prior to a standalone surgical procedure. Standard treatment begins with drug therapy, which has success rates of 30% to 60% (AtriCure cites 50%), making drugs unviable for those with more severe Afib. The second line is cardioversion, which is the process of shocking the heart back into rhythm. Varying sources (Gallagher et al., Knight, the AFA) place the success rate for most patients at above 80% and even above 90%. The third line is catheter ablation, which is a procedure that uses radio waves (RF) or freezing (cryoablation) to scar the heart tissue, hence restoring proper propagation of electrical signals. Per the ACC in June 2013, success rates are 60-80%, and per Harvard Health in April 2018, the "overall success rate for catheter ablation is about 75%. Sometimes, people undergo a second procedure if the first one doesn't work, which boosts the success rate to nearly 90%." As ablation techniques continue to improve with technologies such as 3D mapping and contact force sensing catheters, our view is that today's success rates are generally over 90%, representing a significant hurdle for AtriCure's "minimally invasive" surgical solutions:

Line	Treatment Option	Efficacy / Success Rate	Complication Rate
1	Drug Therapy	50%	< 5%
2	Cardioversion	80%	< 5%
3	Catheter Ablation	75%	< 5%
4	Second Catheter Ablation	90%	< 5%
5	Surgical Ablation	???	???

Thus, we estimate that less than 5% of the diagnosed Afib population ought to pass through all of these lines without success, and thus be candidates for a surgical minimally invasive procedure. A well-known clinical researcher and cardiologist we spoke to believes this figure is even lower, at just 1% to 2% of Afib patients. Independent of the cardiologist, a high-level salesperson at a competitor also stated that just 2% of patients are truly suited for "minimally invasive" Afib surgery.

Note that these figures stand in stark contrast to the Company's figures and rosy projections from the sell side. The Company states the MIS Ablation market is $560 million, which "includes ALL nonparoxysmal Afib patients for whom 'management' has not worked." One sell-side report deriving a ~$600 million market size assumes a 70% failure rate for catheter ablation, which is multiples higher than published rates. Whether this 70% failure rate assumption, which has no basis in fact discernible to us, comes from the company or not, it is clear that expectations expressed both by the company and the analyst community are grossly overstated. If we assume that 15% of patients per year fail catheter ablation (more in line with published rates) and are thus eligible for surgical ablation, then for 2019, this market becomes just $143 million per year, a fraction of the Company's purported TAM.

Also note that through these first four lines of treatment, the patient is in the care of an electrophysiologist ("EP"), rather than a surgeon, hence making it – in our view – rightfully difficult for surgeons to reach patients. However, as we show later in this report, **we found that many of AtriCure's prescribing surgeons engage in direct-to-patient marketing, hence potentially subverting standard lines of care and putting patients at unnecessary risk.** AtriCure's disclosures take a highly detached stance towards these standalone surgeries and physicians doing them, as if physicians act independently from the Company:

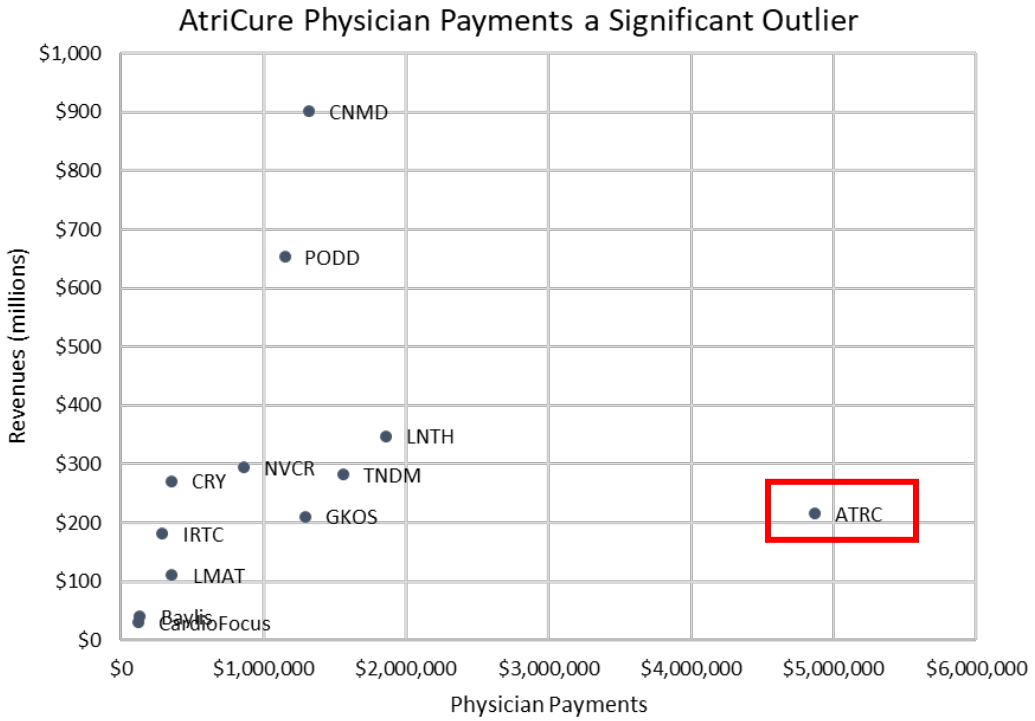
> Physicians may use our products in circumstances where they deem it medically appropriate, such as for the treatment of Afib or the reduction in stroke risk, even though FDA may not have approved or cleared our products to be marketed specifically for those indications … For those patients with Afib who do not require a concomitant open-heart surgical procedure, **surgeons have used our products for minimally invasive Afib treatment procedures** … We do not currently have any products with FDA approved indications for the standalone treatment of Afib. Certain physicians are combining various minimally invasive stand-alone epicardial ablation procedures ... **Physicians are reporting that they are performing these procedures** utilizing certain of our products to primarily treat patients who have non-paroxysmal forms of Afib.

However, we find it extremely difficult to reconcile this detached stance with the fact that over the past 6 years, the Company has paid $19.8 million to physicians, eclipsing peer payments by a factor of 6-7x.

AtriCure Pays Shockingly High Sums to Physicians

Nominal payments for consulting, education, and food and beverage are a normal part of the medical device business. However, from 2013 to 2018, AtriCure paid physicians a remarkable $19.8 million, a level which far exceeds peers. Note we exclude royalty/licensing payments as applicable to compare on a like-for-like basis:

Ticker	Company Name	Market Cap ($MM)	2018 General Payments	LTM Revenue ($MM)	% of Revenues
LNTH	Lantheus Holdings	$857	$1,854,769	$347	0.5%
CNMD	Conmed Corp	$2,809	$1,314,596	$901	0.1%
GKOS	Glaukos Corp	$2,158	$1,290,008	$211	0.6%
NVCR	Novocure Ltd	$9,080	$859,317	$294	0.3%
TNDM	Tandem Diabetes	$3,919	$1,560,372	$282	0.6%
PODD	Insulet Corp	$9,287	$1,147,478	$653	0.2%
LMAT	LeMaitre Vascular	$616	$354,181	$111	0.3%
CRY	CryoLife Inc	$978	$352,082	$271	0.1%
IRTC	iRhythm Technologies	$1,705	$288,392	$182	0.2%
Private	Baylis Medical	N/A	$130,353	$40	0.3%
Private	CardioFocus	N/A	$124,519	$30	0.4%
ATRC	**AtriCure Inc**	**$1,025**	**$4,865,230**	**$216**	**2.3%**
MEDIAN		$2,158	$859,317	$271	0.3%
AVERAGE		$3,490	$843,279	$302	0.3%
Atricure vs. Median		**0.5x**	**5.7x**	**0.8x**	**7.0x**
Atricure vs. Average		**0.3x**	**5.8x**	**0.7x**	**6.8x**



The peer group above includes (1) many of AtriCure's own listed peers per its proxy statement, (2) companies generating more revenue than AtriCure, and (3) companies with higher R&D budgets than AtriCure. Thus, the sheer quantity of physician payments in relation to peers ought to raise questions for AtriCure investors. To this end, we believe an examination of the doctors which AtriCure is paying is also instructive.

AtriCure's "Starting Five"

We now introduce AtriCure's "starting five." Among these highly paid surgeons, we found allegations of a botched heart surgery, wrongful death via a "maverick" surgery, patient negligence, off-label marketing of surgical ablation procedures, failure to disclose financial relationships, and undisclosed marketing relationships. These same surgeons now market directly to patients to the benefit of their own practices and to AtriCure, we believe often to the detriment to patients. As shown in the case studies below, we believe the detached picture that AtriCure attempts to paint – one of physicians acting independently of the Company – is far from reality, and it remains highly concerning that AtriCure is relying on these doctors to drive its business.

1. "The Big Man": Gansevoort "Gan" Dunnington received $1,036,911 from 2013 to 2018

Gan Dunnington is a Napa Valley-based surgeon who has built a substantial portion of his practice on the minimally invasive surgeries done with AtriCure devices. One former employee characterized Dunnington as the Company's "golden goose", without whom the West Coast sales manager would be jobless. Dunnington is clearly important to the Company, as he sat alongside AtriCure CEO Michael Carrel to promote the Company's products on a sponsored segment on "Worldwide Business with kathy ireland®". As a side note, CEO Carrel also promoted the Company on the "RedChip Money Report" in February 2016. RedChip's current coverage includes enterprises such as $2 million OTC-listed Giggles n' Hugs (GIGL), down 99.9% from its mid-2011 highs, and $0.4 million OTC-listed Advantego Corporation (ADGO), down 99% from its mid-2018 highs.

We found YouTube videos of Dunnington promoting the "Napa Valley Atrial Fibrillation Symposium" during which potential patients can "mingle with the experts." A brochure for the event provides for sponsors, of which we believe AtriCure to be chief. Note that several of the surgeons listed as speakers also are high on AtriCure's payroll. We spoke to those familiar with the events, who confirmed that they can attract upwards of 300 patients at a time. Dunnington describes this direct-to-patient marketing regime and implies in an interview that these events draw the "majority" of his patients:

> If we only drew from St. Helena, there'd be no business at all. So we draw from all over Northern California … and then for Atrial Fibrillation, we have people from several states … What they had done is figured out how to go out and educate the public … They'd give seminars … and educating directly to patients … We have a lot of patients because of our outreach education … So the majority of my patients are coming from far away.

It is our understanding that a portion of these patients have never even seen a cardiologist, and that the majority of them have never tried a Catheter Ablation prior to going into surgery with Dunnington.

2. "The Two Guard": Ali Khoynezhad received $735,401 from 2013 to 2018

Khoynezhad was sued in November 2016 for alleged medical negligence in treating a patient, Matthew Brill, who experienced what amounts to a botched heart surgery, causing permanent damage.

In 2018, Khoynezhad was sued by the family of actor Bill Paxton for his wrongful death. The suit alleges that Paxton died from post-surgery complications, namely a stroke, while Khoynezhad operated "beyond the scope" of his experience in treating Paxton with a "needlessly extensive, maverick, and unconventional" surgery.

3. "The Star Rookie": Israel Jacobowitz received $285,947 from 2016 to 2018; $232,743 in 2018 alone

In his prior role as head of the heart surgery program at University Hospital of Brooklyn, Jacobowitz was demoted after the hospital was found to have the second-highest death rate in the state. Per the NY Post, "A state Health Department report in November said Jacobowitz had a rate of 9.96 percent, with three deaths out of 35 bypass operations." In 6 cases in which he could not be reached by staff following post-op complications, 5 patients died. In one case, Jacobowitz accused the hospital of "doctoring the records" of a resultant brain-dead patient.

In a separate March 2003 incident, a jury later found that Jacobowitz failed to practice "good and accepted standards" when he tried a new technique which he wasn't credentialed to use, leading to the death of a patient. Jacobowitz then lost on appeal of the ruling, as "there was legally sufficient evidence to support the jury verdict finding that Jacobowitz and N.Y. Cardio deviated from accepted medical practice…" Interestingly enough, an article citing the case stated that this was a minimally invasive "port access" surgery.

In 2010, Jacobowitz faced another suit alleging negligence in failing to properly monitor a patient post-operation. The suit "alleges the doctor was negligent when he did not detect subsequently high glucose levels to indicate the patient had contracted a post-op wound infection. The verdict resulted in $8.0 million in damages.

4. "The Point Guard": Kevin Makati received $536,793 from 2014 to 2018

We found several presentations wherein Makati explains, discusses, or teaches the Convergent method, such as in 2017, in 2018, and in May 2019. While physicians are free to discuss untested, off-label procedures independently as they see fit, we find that AtriCure remains involved not only through their payments to Makati, but as a direct sponsor of these presentations:

We find it highly puzzling that AtriCure claims "Physicians are reporting that they are performing these procedures" as if physicians act independent of the Company, while the Company also sponsors these presentations. Note that presentations cite AtriCure as supporting "through an educational grant." However, AtriCure made just a single grant payment of $10,600 in 2018, and $4,977 in education payments, as compared to total general payments of $4.87 million. A November 2014 article from Makati's practice states that "Together, the Institute has performed more than 70 procedures. Drs. Makati and Sherman are now training other physicians from around the continental US in the Convergent method" and Makati's LinkedIn confirms he is a "Professional Educator" with AtriCure. Again, this entanglement is a far cry from the detached language in the Company's 10-K cited earlier.

5. "The Franchise Player": Randall Wolf received $700,274 from 2013 to 2018 (2013 is earliest disclosed)

The Company's relationship with Randall Wolf goes back over a decade, as Wolf was responsible for running AtriCure's early FDA clinical trials. However, Wolf was admonished for failing to disclose his financial relationships with the Company, as he stood to benefit from favorable trial outcomes. Per the WSJ,

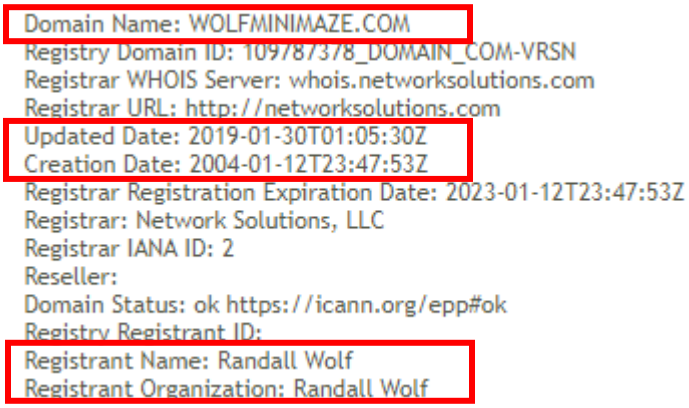
> Not mentioned during the debate or in the disclosure section of the program guide was his seat on AtriCure's board or his investment ties to the company. A Clinic spokeswoman said his secretary mistakenly checked a box on a disclosure form indicating he had no conflict.

AtriCure stock subsequently fell over 20% as hospitals balked at their relationships with the Company. In more recent years, Wolf remains on the Company's payroll. We also discovered a live website "WolfMiniMaze.com" which offers potential patients with information about the Mini Maze (minimally invasive surgical) procedure, as well as advertises "Patient Experience Seminars" similar to those hosted by Dr. Dunnington:

The website states:

> In 2004, after remaining AFib-free following the Wolf Mini-Maze procedure, **one of our patients surprised Dr. Wolf by creating this website**. His intention was to help others learn more about treatment options for AFib so that they could experience the same quality of life that he had regained.

However, a simple check of the website's registry indicates that it was registered by Dr. Wolf himself, not one of his former patients:



We find these connections to be misleading at best and deceptive at worst, which is troubling given the focus of the site. The photo above shows at least 50 people, while contacts report that these seminars (similar to Dr. Dunnington's) can gather hundreds of potential patients. As the site itself is named "Wolfminimaze.com" we expect that the intention of the seminars is to guide patients towards surgical procedures.

"The Sixth Man": Mellanie True Hills of StopAfib.org

The Company also appears to have connections to an individual named Mellanie True Hills, who runs "StopAfib.org." The site is owned by a non-profit foundation named the "Foundation for Women's Health" and provides various information regarding Afib treatment options, surgeons, and more. The site also offers a sponsorship service, allowing healthcare providers to "provide reviews and … [have patients] learn about you" such that the provider can "start attracting more patients."

Echoing our view of Dr. Wolf's Wolf Mini Maze site, we have concerns around the ethics of this direct-to-patient marketing. A doctor named Wes Fisher who is a "board certified internist, cardiologist, and cardiac electrophysiologist" wrote an article about the site back in 2007 alleging that AtriCure its sponsor. An addendum to his original article stated that Ms. Hill admitted as much:

> *15:15PM CST Addendum: I contacted Ms. Hill regarding this post and she was very nice to respond. She did confirm that Atricure contacted her first and had a particular interest in her skills as an "author, writer, and speaker," and they shared ideas and it was her idea to provide a forum for patients to explain options for atrial fibrillation therapies and ways to prevent strokes. Hence they provided a grant to her. She states Atricure was "very careful" to remain detached from the project. She also noted the "EP's had a vested interest" in performing catheter-based afib ablation procedures and often refused to refer patients for surgical procedures. She is continuing to seek other sponsors for her website.*

Form 990's (non-profit financials) for the "American Foundation for Women's Health" indicate that the foundation has received a cumulative $2.25 million in gifts, grants, and contributions from 2013 to 2017 (latest available). While the 2017 contributor disclosure list was blank, the 2016 list indicates that there is merely a single donor of substance (disclosures must be made for any donation over $5,000):

Schedule B (Form 990, 990-EZ, or 990-PF) (2016) Page 2

Name of organization	Employer identification number
American Foundation For Women's Health	20-1338371

Part I Contributors (See instructions). Use duplicate copies of Part I if additional space is needed.

(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
RESTRICTED		$ RESTRICTED	Person ☐ Payroll ☐ Noncash ☐ (Complete Part II for noncash contributions.)
(a) No.	(b) Name, address, and ZIP + 4	(c) Total contributions	(d) Type of contribution
		$	Person ☐ Payroll ☐ Noncash ☐ (Complete Part II for noncash contributions.)

Given AtriCure's original ties to the site, we question who this unnamed donor is.

"Minimally Invasive" Procedures are Highly Profitable, Especially When Double-Billing

Per doctors' own admission, these procedures are also highly-profitable for their practices. See the following from David DeLurgio at the Company's 2018 Investor Day in response to hybrid procedures:

> My hospital wants me to do more. So they're happy. As a matter of the fact, the way we do our hybrid procedure is all same-day and the reimbursement is based on the DRG of the surgical AF ablation, which essentially covers us both and they're very happy with that. **You can split them up. Some people have done that. And if you split them up by enough time, they can both be billed.** And as it stands currently, it is a financially successful procedure for the hospital to perform. So they like to see them done more, which is not something we can always get them to admit. We still have a problem with the clip. That's something that we have to work on.

Note that from 2015 to 2018, DeLurgio received a total of $96,365 from the Company. Regardless, DeLurgio divulges an interesting fact regarding reimbursement, which is that "You can split them up. Some people have done that. And if you split them up by enough time, they can both be billed." While investors have glanced over these statements or even seen them as a positive, we see no other way to frame these statements except as a tacit admission that at least a portion of AtriCure's customer base is double-billing for the procedures.

Per reimbursement guides and channel checks, we believe "enough time" to mean over 90 days, after which these staged procedures are billed as if it was in fact two procedures rather than two stages of a single procedure. This high reimbursement has been alluded to on AtriCure's conference calls, with one sell-side analyst citing a $50,000 figure, while former employees of the Company confirmed to us that the coding for the first surgical part of the

procedure is done under open heart codes, even as these are supposedly minimally invasive surgeries, again illustrating their highly invasive and risky nature. See from the Company's own reimbursement guide:

Table 2. Inpatient Facility Coding and Reimbursement

The site of service depends on the patient's chief complaint, clinical presentation and is solely determined by the admitting physician. The ICD-10-CM (Internal Classification of Disease, Tenth Revision, Clinical Modification) Diagnosis Code(s) and primary ICD-10-PCS procedure code(s) determine the MS-DRG (Medicare Severity Diagnosis Related Group).

MS-DRG*	Description	Weight	Arithmetic mean LOS	CY 2019 Inpatient National Standardized Prospective Payment
Cardiac Surgical Ablation				
228	Other cardiothoracic procedures with MCC	6.576	9.7	$37,152.37
229	Other cardiothoracic procedures without MCC	4.648	4.7	$26,261.23

After the surgeon performs his portion, the EP can do his portion of the surgery over 90 days later, billed under the following:

Table 3. Outpatient Hospital and Ambulatory Surgery Center Reimbursement

When a percutaneous ablation procedure is performed, the corresponding APC (ambulatory payment classification, similar to DRG for inpatient) for in hospital outpatient prospective payment system (HOPPS) may include:

CPT	Procedure Description	Comprehensive APC*	APC Title	CY 2019 Medicare National Standardized APC Payment (HOPPS)
Percutaneous Catheter Ablation				
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording (when necessary), His bundle recording (when necessary) with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	5213	Level 3 EP Procedure	$19,213.74
93654	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording, His recording with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed			
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right ventricular pacing/recording when necessary, and His bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation			

We sought to find a clinical justification for an extended wait time of 90-plus days, but came up empty. See the following studies which performed the two-step procedures; in only 1 of 8 was the trial designed to wait 90 days before completing the second stage, with none over 90 days:

Author	Time
Bulava	6 to 8 weeks
Pison	Immediate
Kurfirst	3 months
Bilseri	30 to 45 days
Gehi	Immediate
Mahapatra	3 to 5 days
La Meir	Immediate
Staged DEEP	1 to 10 days

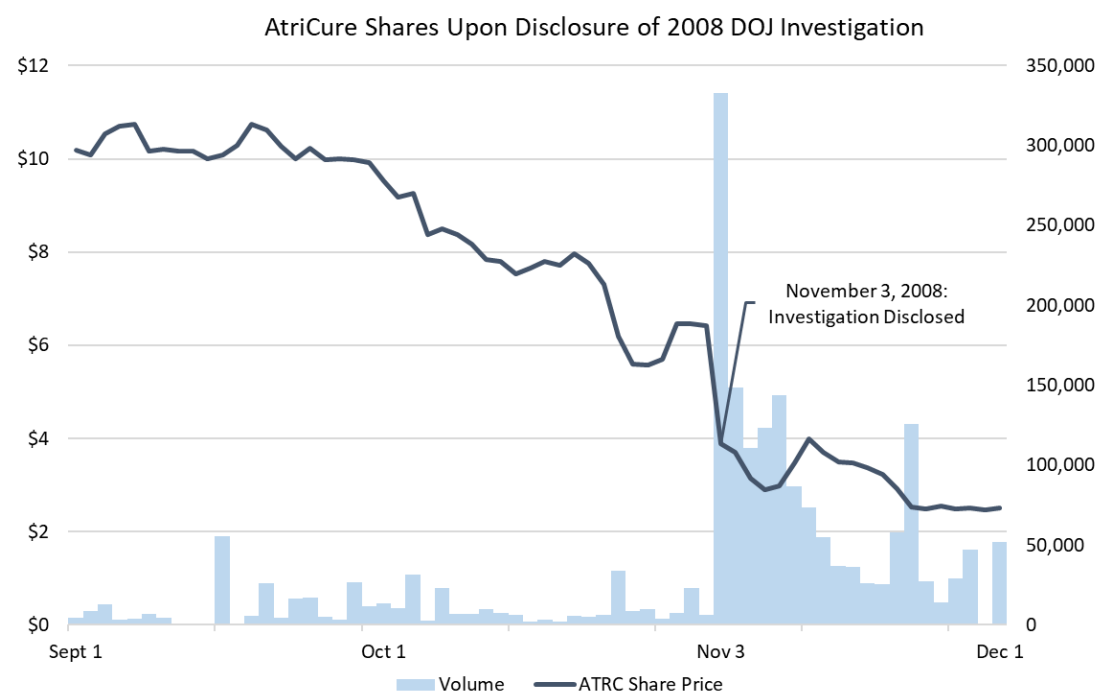
In fact, a 2016 study showed no difference in clinical outcomes for staged procedures vs. immediate catheter ablation (CA). Thus, we find it all the more likely that the explanation for this wait period lies merely in the expectation of more attractive billing / reimbursement. We question why these patients ought to wait an additional 90 days-plus to complete the procedure, especially as catheter ablation takes just 1-6 hours with recovery times of just a few days. As we now show, the DOJ is investigating and has issued a CID to AtriCure. We believe that as the structural deficiencies to the Company's MIS business are revealed through the DOJ investigation, the Company's long-term growth narrative ought to unravel.

AtriCure and the DOJ: We Meet Again

In December 2017, the Company received a Civil Investigative Demand (CID) from the Department of Justice (DOJ) relating to the off-label marketing and use of its products. The Company's disclosures state (author emphasis):

> On December 11, 2017, the Company received a Civil Investigative Demand (CID) from the U.S. Department of Justice (DOJ) stating that it is investigating the Company to determine whether the Company has violated the False Claims Act, relating to the **promotion of certain medical devices related to the treatment of atrial fibrillation for off-label use** and submitted or caused to be submitted false claims to certain federal and state health care programs for **medically unnecessary healthcare services related to the treatment of Afib**.

Per the Company, this CID was not deemed material such that it would need to be disclosed when received; rather, the receipt of the CID was only disclosed in the Company's Form 10-K filed March 2018. Given AtriCure's experience with its 2008 DOJ investigation, it's reasonable to understand why the Company waited so long to disclose this fact: shares closed down 39% on 37x the usual volume on the day of the 2008 DOJ investigation disclosure, while over the next 14 trading sessions, shares fell a total of 61% on a total of 10x the average trading volume prior to receipt of the investigation:



The original August 2007 qui tam complaint against the Company can be found here. The complaint cites a variety of tactics that the Company allegedly used in an "aggressive off-label marketing campaign." Note that the campaign focused on the Bipolar Surgical Ablation system, which as we referenced earlier, was used both in concomitant settings and tested as a standalone solution (see DEEP AF, Staged DEEP, and HT2AF trials) prior to the Company's current focus on the Epi-Sense (see CONVERGE). The result of this campaign was that "a substantial number of patients have undergone more intensive, inpatient surgical ablation procedures, where less intensive, outpatient catheter ablation procedures (or other treatments) should have been performed instead." AtriCure settled with the DOJ in February 2010 for $3.76 million.

Interestingly, this new Civil Investigative Demand "covers the period from January 1, 2010 to the present" (per the 2017 form 10-K), which is just prior to when the Company previously settled with the DOJ. Thus, we believe that the DOJ is "circling back" on its original settlement, as it has reason to believe that AtriCure is once again in the wrong. Given that it has now been ~10 months since CID receipt, we believe the DOJ will act sooner rather than later, and resolution ought to result in both (1) monetary fines, (2) more rigorous ongoing monitoring of business practices such as is found in a consent decree, and (3) reputational damage to the Company.

Additional Red Flags

SentreHEART Acquisition Illuminates AtriCure's Challenged Position

In August 2019, AtriCure announced an agreement to acquire SentreHEART, Inc., which develops left atrial appendage (LAA) management solutions. The acquisition will include $40 million in cash and stock up-front and two contingent consideration payments of $140 million related to the aMAZE IDE clinical trial and $120 million "based on a milestone related to reimbursement for the therapy involving SentreHEART devices."

With the acquisition announcement, the Company guided 2019 to an EBITDA loss of $7 to $9 million, and less than $10 million loss in 2020, with management stating that "beyond that, we haven't given guidance on an exact time frame for EBITDA 2020 profitability beyond." The Company's associated presentation consistently notes entry into the EP market as key to the strategic rationale, which we can understand given the Company currently interfaces primarily with surgeons, while EPs remain the "gatekeepers" to patients. Nevertheless, analysts had valid concerns surrounding the Company's implicit admission that its own solutions were lacking, potential for cannibalization, concerns over the LARIAT's previous FDA notice regarding adverse events, and the pushed-out path to profitability. The stock's fall from the $30-31 range to $26-27 today appears to be driven in large part by these concerns.

Questionable Conditions Surrounding Synergy Ablation System PMA Approval

It is worthwhile to note the bizarre conditions surrounding the Company's original PMA approval for the Synergy Ablation System, which forms the core of the Open (concomitant) business. The study used in support of said approval was the "ABLATE" study, or "AtriCure Bipolar Radiofrequency Ablation of Permanent Atrial Fibrillation (ABLATE)." Per the study,

> ABLATE is a prospective, non-randomized multi-center clinical trial to demonstrate the safety and effectiveness of the AtriCure Bipolar System for treating permanent atrial fibrillation during concomitant on-pump cardiac surgery.

We found that the FDA's Safety and Effectiveness summary indicated that excluding the paroxysmal patients, **the study failed its primary safety endpoint for the non-paroxysmal (i.e. long-standing and persistent Afib) group:**

> Based on the results presented in the table above, the primary safety endpoint is met for the Treated population, but not for the Non-Paroxysmal subgroup.

These results are highly concerning given that **the System is intended to treat those with more severe forms of Afib**. This study was used to support the Company's push to receive FDA approval for its synergy bipolar RF clamp, as it was presented to the panel by Dr. James Edgerton. Note that Edgerton received $108,442 from AtriCure from 2014 to 2018. However, the FDA did push back:

> In terms of safety, the panel voted **five to four, with one abstention, that the ABLATE data provided reasonable assurance that the Synergy clamp was safe.** Overall, the panel voted five to three, with one abstention, that the benefits of AtriCure's Synergy clamp outweighed the risks in treating patients with persistent and longstanding persistent Afib.

> In addition, **four of the patients were later deemed by independent reviewers to have paroxysmal atrial fibrillation.** FDA representatives expressed concern that the four paroxysmal patients may have been healthier than the persistent or longstanding persistent Afib patients in the study, **which could have made the Synergy clamp's safety appear better than it is.** Presumably, the FDA and AtriCure will continue their discussion of the safety events recorded in the trial and to what extent AtriCure's proposed surgeon training program can reduce the number of complications.

Thus in 2011, the Company was granted approval for surgical ablation on the condition of a PMA, or "pre-market approval." A PMA is "the most stringent regulatory category for medical devices," per the FDA. As such, the Company's the device required an extensive 350-patient follow-up study to evaluate safety and effectiveness. Links to that study can be found here (ClinicalTrials.gov) and are on their third round of quality control reviews:

Submission Cycle	Results Submitted to ClinicalTrials.gov	Results Returned after Quality Control Review
1	October 29, 2018 (Canceled on October 30, 2018) March 10, 2019	June 14, 2019
2	July 15, 2019	August 6, 2019
3	August 12, 2019	

Though these rounds of quality control review do not necessarily indicate issues in the results of the study that would put AtriCure's Open Heart business at risk, we remain eager to see the results given the conditions surrounding the original approval.

Management Track Record of Value Destruction

Outside of the US, the Company's strategy is weak at best. Even though the Company cites "product expansion in Asia" as its first key growth driver in its investor presentation, AtriCure is now in the midst of a lawsuit with its former Chinese distributor. The Company alleges that the ex-distributor took its inventory without ever paying for it, used that inventory to steal its IP and create its own products, and never obtained regulatory approval to sell its products in China despite the distributor's promise to do so.

These issues exemplify a management team that we believe is in over their heads. CEO Michael Carrel has very little experience relevant to running a billion-dollar medical device business. He was formerly CFO, then CEO of Zamba Solutions (OTC:ZMBA) which was a dot-com stock that, per a lead investor, "should have been dead 40 times over." Carrel gave an interview detailing the history of the company, which raised hundreds of millions in capital before finally selling to a Chicago-based consulting group named Technology Solutions Co (OTC:TSSC) for just $6 million. TSSC now trades at a sub-million-dollar market cap.

Carrel then joined Vital Images (VTAL) in January 2005 and became COO and CFO in May 2005, advancing to the CEO post in January 2008. In 2005, Vital Images posted $52 million in revenues and $11.6 million in EBITDA. In the LTM ended March 2011 (prior to acquisition), the company posted $60 million in revenues and just $1.6 million in EBITDA. The company IPO'd in November 2006 at $31 per share and was acquired in April 2011 for just $18.75 per share (closed June 2011). Carrel stated of the acquisition price that "Quite simply, it was a really good price for our shareholders." Given VTAL's sales stagnation, deterioration in profitability, and ultimate acquisition price

under Carrel's purview, we'd be hard pressed to characterize his tenure as value creative. Interestingly, Carrel also brought over a portion of his Vital Images team to AtriCure. Given this history, we believe AtriCure's team is ill-equipped to handle the outstanding risks to its business model.

Recurring Claims of Profitability Never Satisfied

We also found a troubling history of statements regarding the Company's path to profitability that have not been met over time. See from the Q4 2012 conference call, February 28, 2013:

> Q: Okay. That's helpful. And then … this cash raise, how do we think about cash position to get you to profitability? Will you have to go back to the market or are you guys still comfortable where you are at this point?
>
> Michael H. Carrel: **We feel very comfortable** where we are right now.

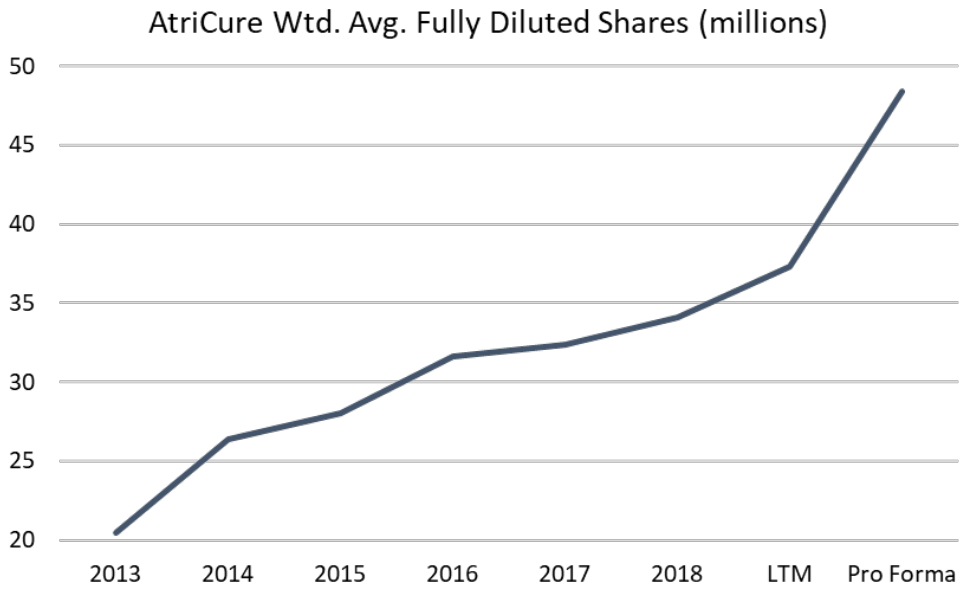
JP Morgan conference January 2017:

> And then, as we look forward to 2017, I think it's important to note that we, as a company, are on the cusp of profitability … For 2017, we are going to more than cut that in half to a $4 million to $6 million EBITDA loss for the year and **we'll be EBITDA profitable in 2018.**

JP Morgan conference January 2019:

> And again, from a financial standpoint, you can also see that not only have we grown our top line, but we've started to get leverage on the bottom line. And you can see that this year, we've got about $1 million to $3 million EBITDA loss, and **in 2019, we will be profitable.**

As noted above, in August 2019, the Company announced that it was taking down EBITDA guidance once again. Meanwhile, share count continues to rise, with the Company having most recently raised $83 million in late 2018 at $30.75 per share. Share count below includes a pro forma count for the SentreHEART acquisition at 100% stock:



AtriCure is Worth $11.32 Per Share, 57% Less Than Today

Due to the risks to the Company's business model enumerated above, we believe AtriCure ought to trade at no more than $11.32 per share today, or 57% downside. The Company's open heart business remains under structural pressure, while the challenges and true drivers of its MIS business will become clearer in short order. Our valuation assumes 8.9% revenue growth, while supposing the Company can generate 20% "run-rate" EBITDA margins by 2023, even though the Company guided to continued negative EBITDA through at least 2020. We include the effects of the SentreHEART acquisition which has now closed, which will increase share count by 30% (assuming all equity). Further in the Company's favor, we also exclude the effects of interim cash burn and SBC-based dilution:

	$ millions	*Commentary*
2019 Revenues Est.	227	*consensus estimate*
2019 EBITDA Est.	(9)	*management guide*
2023 Revenues Est.	320	*8.9% growth CAGR*
2023 EBITDA Margin	20.0%	*in-line w/ scaled peers*
2023 EBITDA Est.	64	
EBITDA Multiple	12.0	*generous given risks*
2023 Enterprise Value	768	
Present Net Cash	33	
PF 2023 Market Cap	801	
Current FD Shares O/S	37.3	
SentreHEART Issuance	11.4	*$300 million @ $27.30/share*
PF 2023 Shares O/S	48.7	
2023 Value per Share		**$16.43**
Present Value per Share		**$11.22**
Downside		**-57%**

We expect that the DOJ investigation will result in more rigorous ongoing monitoring of the Company's activities, which could restrict the scope of what we have outlined in this report. This ought to impair the Company's MIS segment, where both management and investors have placed their hopes. We believe that these hopes, like many of the "minimally invasive" surgeries themselves, will ultimately prove misplaced.