August 11, 2020

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August 11, 2020

STARR Surgical (STAA)

Less Than Meets the Eye

The residential compound where Shanghai Qinghong Trading Co. Ltd., a distributor of STAAR products in China, is registered. The compound is over 50 km from Shanghai city center. Guard would not allow us to enter. Photo by J Capital July 2020.

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We think that STAAR Surgical has overstated sales in China by at least one-third, or $21.6 mln. That would mean that all of the company's $14 mln in 2019 profit is fake.

A single Chinese distributor accounted for 43% of STAAR's total sales and 71% of its growth in 2019 and over half in Q2 this year. In the 2019 10K, STAAR reports: "One customer, Shanghai Langsheng [sic], our China distributor who sells in to China and Hong Kong, accounted for more than 43% of our consolidated net sales during fiscal 2019." [1]

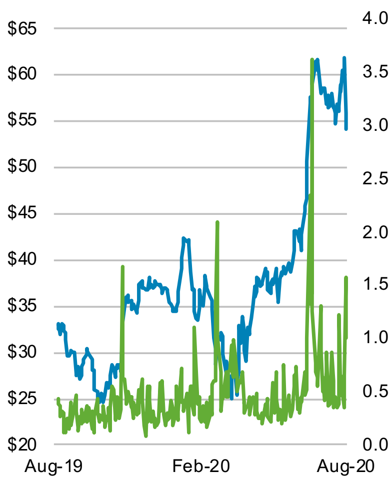
1 The proper spelling of the distributor is Lansheng.

August 11, 2020

STAAR Surgical (STAA)

Share Price in USD	**$54.16**
Market Cap in USD (mln)	$2,319.00
Av volume (shares)	675,433
Price/Sales	15.8x
Price/Ebitda	123x

STAAR Surgical (STAA) last share price in USD (blue, left) and volume (green, right, mln shares)



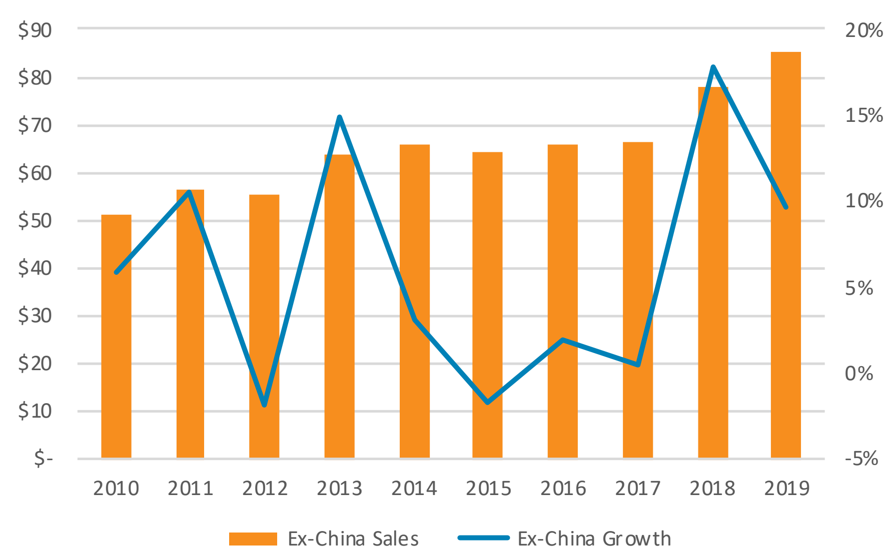
Source: S&P Capital IQ August 10, 2020

Unfortunately, the Chinese numbers (which are not audited [2]) are unreliable.

STAAR makes Implantable Collamer Lenses (ICLs) to correct severe myopia. ICL surgery is about three times as expensive as the more common LASIK procedure, and high out-of-pocket costs tend to discourage all but the most myopic.

Ex-China, STAAR sales growth has been unremarkable, yielding a 5% CAGR for the last decade, and profit has mostly been elusive despite 38 years in business.

Chart 1. Ex-China STAAR Sales (mln USD) and YoY Growth



Source: STAAR financial statements

But China sales show a 37% CAGR over that same period. That growth has driven up the share price.

2 See the PCAOB website. The Chinese affiliate of STAAR's auditor, BDO, is not involved with the STAAR audit. BDO may not conduct audits in China directly. https://pcaobus.org/issuers/17702/718937

Chart 2. China Revenue Growth, Total Revenue Growth, and Share Price (LHS, in USD)

Source: Company disclosures, S&P Global

After extensive research into STAAR's worldwide operations, with a focus on China, we have concluded that STAAR China sales are overstated by about 33%. Fake sales come at 100% margins and therefore translate directly into profit. That means that the roughly $21.6 mln in overstated Chinese sales in 2019 represent 152% of total company profit. In other words, without the fraud that we believe pervades the China business, STAAR is losing money.

We have conducted over 75 interviews, visited company sites in China and Switzerland, and reviewed financial statements and other government documents for STAAR's distributors and customers in China. We will show that sales of STAAR's ICLs are dramatically overstated.

The overstated sales

We offer four types of evidence:

- Financial statements of the largest Chinese client, Aier Eye Hospital, indicate that those clinics bought only about half as many lenses as STAAR's distributor claims. Aier represents about half of China sales and 25% of total sales, according to our interviews.

- Public data show that the value of lenses exported from Switzerland, the source of all product STAAR sells in China, is far lower than the reported sales.

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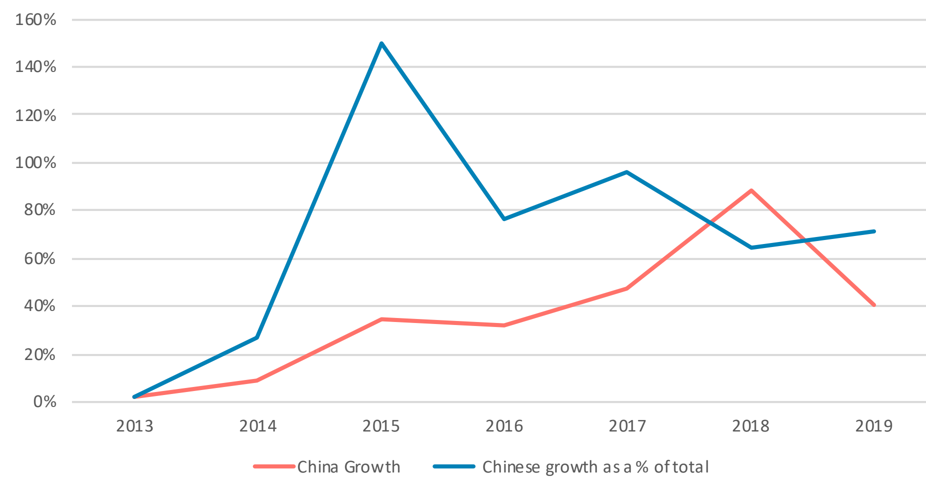
- In interviews, Lansheng's Tier 2 distributors told us how many lenses they sell, and the numbers suggest a lower volume than claimed.
- Inventories, PPE, and manufacturing activity do not appear to support large annual volume growth.

Chart 3. STAAR China Growth as a % of Total



Source: Company filings

The biggest client not so big

STAAR has not said much to investors about its largest client, Aier. It has posted a public notice in some Aier clinics stating that Aier has been the largest ICL partner each year since 2015.

We spoke to a dozen people familiar with STAAR's sales in China, and they agreed that the STAAR sales numbers assume that 65,000-75,000 lenses—half the volume sold in China--were sold to Aier Eye Hospital Group (300015 SZ) in 2019.

But Aier's public financial statements indicate that its purchases from STAAR should be no more than 41,192 lenses, 43% fewer than our interviewees told us.

Based on Aier's 2019 annual report and our interviews with Aier management, we estimate that Aier performed at most 20,596 ICL surgeries in 2019. This is based on Aier IR, which told us that 15-20% of "refractive surgery" revenue comes from ICL implants—we took 17.5% of Aier's reported refractive surgery revenue for 2019. IR also told us that the ICL surgeries cost about ¥30,000. Based on those two data points, we calculate 20,596 ICL surgeries in 2019. If all the surgeries involved two lenses, then STAAR

The notice above, posted in an Aier clinic in Beijing, reads “As a division of Staar Surgical AG in Greater China, STAAR Optical Equipment Technology (Shanghai) Co., Ltd. hereby verifies that Aier Eye Hospital Co. Ltd. has been Staar Surgical’s largest global partner for the implantation of ICL lenses for five years running, 2015, 2016, 2017, 2018, and 2019.” | Photo by J Capital August 2020.

sold at most 41,192 lenses to Aier in 2019, not the 65,000-75,000 that Lansheng and STAAR China told us.

Our interviews with Lansheng and Aier procurement found that Aier pays an average of at least $585 per lens, and Lansheng receives a roughly 17% commission on the Aier sales. For 41,192 lenses, that would mean $20.2 mln in revenue to STAAR in 2019, not the $32.4 mln that would represent half of China revenues.

Table 1. Aier ICL Purchase Calculation

	Aier reported 2019
Est revenue from ICL procedures (mln RMB)	¥617.88
Average surgery price	¥30,000
Est number of surgeries	20,596
Est number of lenses (@2 per surgery)	41,192
Aier average lens price in USD	$585
Est commission to Lansheng	16%
Total Revenue to STAAR for Aier lenses 2019 (mln USD)	$20.24

Source: Aier 2019 AR, Aier IR, STAAR reports, Lansheng interviews

Aier has ample means to obfuscate its lens purchases. We learned in an interview with an Aier executive that the company has a subsidiary at a non-existent address in Tibet that is dedicated to processing purchases of STAAR lenses. This company, called Shannan Youshi ("Improved Vision") Medical Equipment Co. Ltd., pays STAAR for lenses and takes payment from the Aier hospitals, with little scrutiny of accounts; Tibet is notorious for providing operational opacity to companies.

Government registration record via Qixin

We asked a photographer to visit the premises, but the address does not exist. We telephoned the registered phone number, and it was a non-working number.

Aier reported impressive growth in revenue from refractive surgeries in 2018 and 2019, but the growth was well below what STAAR reported in revenue growth for China. In 2018, Aier reported 46% growth in refractive surgeries compared with STAAR's report of 88% growth in China revenue, and in 2019, Aier reported 26% growth, against STAAR's report of 41% growth in China.

Even before the Covid-19 crisis, our interviews with Aier doctors and Lansheng formers indicated slowing growth in sales. A former business manager at Lansheng told us in August 2019: “Aier demand is flattish. People are much more interested in LASIK. People feel nervous about having an implant.”

In Q1 2020, Aier reported that its revenues dropped by 27% YoY and profit declined by 73%. Most clinics across China were closed for elective procedures from late January through March. Yet STAAR reported that its China ICL unit sales for the quarter rose by 7% year on year. We checked with two distributors to see whether they had stockpiled inventory, and the answer was no. Nor is there inventory at hospitals. “Public hospitals do not carry inventory,” one of the distributors said to us.

Aier executives told us that 10 of their hospitals do carry inventory, but Aier’s financial statements indicate that inventory was flat in Q1 2020 on Q4 2019. That means the 7% reported growth is unlikely.

The plug

STAAR compensates for this sales inflation, we believe, with the marketing budget, which was $45.5 mln in 2019, 30% of sales. We spoke with sales and marketing executives in China, in the U.S., and in Europe as well as with former C Suite executives, and none could identify promotional spending nearing $45.5 mln a year. These executives, including longtime regional sales directors, told us they estimate that the company spends no more than a couple million dollars on marketing. Local marketing costs are borne by the distributors.

Instead, according to a highly placed former executive, STAAR inflates sales and then balances the “income” by marking up marketing costs. According to a former executive, marketing “subsidies” may be around one-third the stated value of the lens, so that the distributor buys the lens at $300 but STAAR books the sale at $450 and in order to hide the phantom revenue allocates the $150 to marketing. This means that STAAR is able to toggle sales at will using its marketing budget.

STAAR’s marketing budget is completely out of proportion to its costs. STAAR supports conferences and doctor training, but in China, we could identify maximum $500,000 annually in training expenses. We purchased a credit report on STAAR China and found that that company paid out just $127,698 in marketing expenses in 2019. Yet China represented 43% of STAAR’s sales in 2019.

达视光学设备技术（上海）有限公司

项 目	行次	本年累计数
一、主营业务收入	1	37,290,079.35
减:主营业务成本	2	34,241,069.21
主营业务税金及附加	3	62,199.81
二、主营业务利润(亏损以"-"号填列)	4	2,986,810.33
加:其他业务利润(亏损"-"号填列)	5	0.00
减:营业费用	6	889,765.41
管理费用	7	1,302,731.10

Source: China Tax Department

China sales volumes fall short

We interviewed both Lansheng and its sub-distributors about their sales volumes. When we totaled up the numbers they gave us in interviews, we found volumes fell short of what they would have to be to rack up $64.8 mln in sales. Based on the prices Lansheng pays STAAR for lenses—which we have confirmed with STAAR formers—the company should have sold 129,000 lenses in 2019. But we counted only 70,050 in total, including the 41,000 we estimate Aier purchased.

Lansheng has eight Tier 2 distributors. Two of those are shell companies associated with STAAR and Lansheng staff that do not appear to have staff. The other six companies each estimated 2019 sales volumes for us in interviews.

Table 2. Interviews on Lens Sales 2019

Company Name	Number Sold in 2019	Note
Shanghai Leyue Optical Equipment Co., Ltd.		Owned by former STAAR staff
Guangzhou Shiran Medical Equipment Co., Ltd.	3,000	2019 sales rose by 30%
Beijing Jiashikang Technology Co., Ltd.	8,000	
Changsha Tianzhi Medical Equipment Co., Ltd.	12,000	
Shanghai Qinhong Trading Company		Owned by Lansheng owner. No staff or physical presence.
Shenyang Wanli Road Technology Co., Ltd.	500	"Very low sales"
Shaanxi Shangbo Trading Co., Ltd.	1,800	
Chongqing Shangzhou Medical Devices Co., Ltd.	2,750	
Total Inventories	1,000	
Total Lenses	29,050	

Source: J Capital Research

In total, those six companies said they sold about 29,050 lenses in 2019. The total of estimates for Aier and the Tier 2 distributors is 70,050 lenses.

Source: Chinese government record via Qixin

STAAR Greater China Director Liu Juan giving a talk. Liu Juan is the independent director for Shanghai Leyue, which Lansheng says is its largest Tier 2 distributor. Source: Shanghai Heping Hospital.[3]

3 https://www.hpyk.com/ynxw/16725.html

The largest Tier 2 distributor is Shanghai Leyue Optical Equipment Co. Ltd., which was set up by former STAAR China sales staff. According to Lansheng, Leyue sells 20% of the lenses consumed in China and is the agent for Shanghai, Zhejiang, Jiangsu, and Anhui provinces. The principal owner, Pan Jie, is former regional sales director for STAAR according to three of our interviews, and company Independent Director Liu Juan, pictured above giving a talk at a STAAR event in 2016, is former China director for STAAR.

But our visit and calls indicate that the company does not have any real operations. When we called, the person answering the phone refused to identify the company. We asked to speak with a salesperson and were refused. The receptionist refused to provide us with an address or product brochure. When we visited the registered office location, the company's name was nowhere to be seen. A different company called Shanghai Chengwei Interior Decoration Co. is at the same address. The office does display a poster showing the STAAR EVO lens.

Left: hallway outside Leyue office. Right: Mixed office and residential building where Leyue is located. | Photos by J Capital Research July 2020

The second shell-company distributor is Shanghai Qinghong Trading. Lansheng staff say that Qinghong is the distributor for Shandong, Tianjin, Henan, and Hong Kong. Government documents show that Qinghong is owned by Lansheng's chairman, Zhang Jian. We were unable to find any staff for this company. The company telephone is the same as that for Lansheng Resources, as is the website. The company office does not look like it belongs to a major medical distributor.

Missing exports from Switzerland

All product shipped to international markets is shipped from a STAAR facility in Nidau, Switzerland, which mostly repackages products made in STAAR's Monrovia, California factory. Lansheng, which accounts for 100% of China sales, imports all STAAR ICLs from Switzerland. But Swiss records showing exports of implantable contact lenses to China indicate sales far lower than those claimed by STAAR.

Swiss export records[4] show just $23.5 mln in exports of implantable contact lenses to China for 2019, compared with STAAR's reported China sales of $64.8 mln. The exports to Hong Kong are de minimis, so the gap cannot be explained by gray-channel imports through Hong Kong or by the margin Lansheng makes.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Homepage

Swiss-Impex | My files | Profile | News | Help | Statistics method | Media information

Results table

Options | Edit request | New request

Caption
* Percentage change/share/price not interpretable or not calculable
** Percentage change > 999.9 %
*** Provisional data
[1] Since 2002: including electricity, returned goods and goods for processing without change of ownership

9021.9000 - Articles and appliances, which are worn or carried, or implanted in the body, to compensate for a defect or disability, and parts and accessories of articles and appliances of heading 9021 (excl. artificial parts of the body, complete hearing aids and complete pacemakers for stumulating heart muscles)

Period [1]	Commercial partner	Export			
		Quantity (kg)	Quantity +/- %	Value (CHF)	Value +/- %
January 2020***	China	196	-75.4	302,982	-79.7
February 2020***		189	-72.5	359,443	-72.5
March 2020***		261	-64.2	337,489	-67.7
April 2020***		29	-96.8	93,777	-92.6
May 2020***		50	-95.7	44,133	-97.8
June 2020***		90	-92.5	121,066	-95.0

Screenshot from Swiss-Impex August 2020

4 Data can be found on this website: https://www.gate.ezv.admin.ch/swissimpex/index.xhtml. We believe the most relevant category is 9021.9000.

Table 3. 2019 Swiss Exports to China of HTS 9021 Implantable Lenses

Total Value in CHF	21,436,831 CHF
Total Value in USD	$23,583,443
STAAR reported sales to China 2019	$64,800,000
Difference	63%

Source: Swiss-Impex, STAA disclosures

The figure likely understates STAAR sales in China due to issues of categorization or tariff "minimization."

The Swiss statistics do not provide a precise estimate of China sales, but they do support our view that sales are lower than claimed. We found supporting evidence by visiting the Nidau facility, where activity seems too slow to support the company's contention that 88% of its total product is shipping from that location.

Our investigator visited STAAR's facility in Nidau and offices under construction a few minutes away in Brugge. He spoke with employees and people in the neighborhood estimated that about 20 people work in manufacturing, packing, and shipping for STAAR on the site. This compares with 45 staff reported for STAAR Nidau in an article that appeared in Switzerland's Neue Zürcher Zeitung in 2000, when STAAR was renting the same premises.[5] In other words, STAAR staff in Nidau has declined over a 20-year period.

5 The German-language article can be downloaded here: https://jcapitalresearch.box.com/s/xtmfmdg6ovbb6yfx2cjec9k9iyp3n2bu

Loading dock at the Nidau facility. | Photo by J Capital June 2020.

STAAR has recently rented a new facility in Brugg, a three-minute drive from Nidau, for administrative offices and is moving some manufacturing to Nidau.

The Brugg facility. | Photo by J Capital June 2020

Nidau facility under construction. | Photo by J Capital June 2020

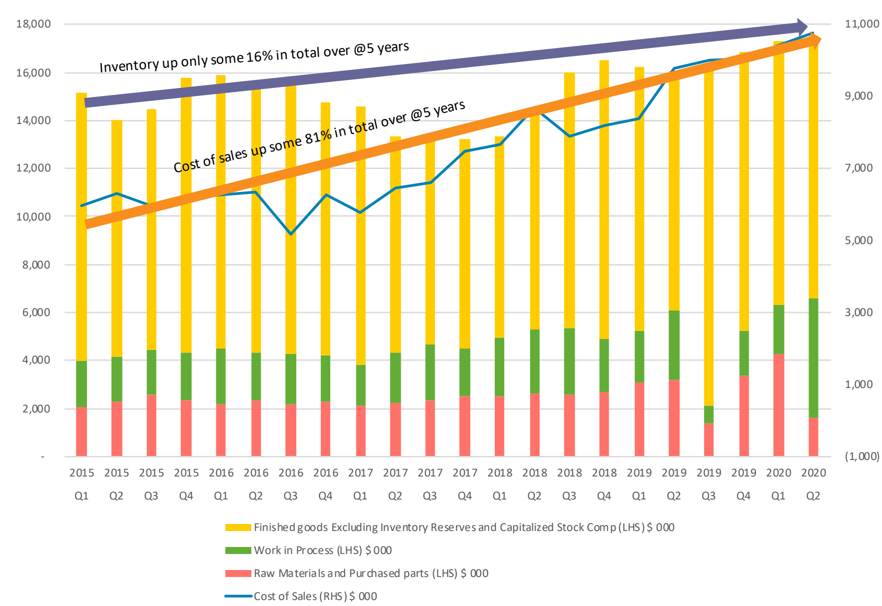
Underwhelming manufacturing levels

We think STAAR may be producing fewer lenses than it claims. Inventories have actually declined over five years despite a 95% increase in income. The dollar value of work in process has declined 6% in five years, falling every year except 2018. They have not disclosed changes to the method of classification for inventory.

Because prices were dropped significantly in 2015-16, according to our interviews, volume must have increased even more than the 95% realized in income growth. Yet there is no build-up of raw materials, no staff additions at the Collamer plant in Aliso Viejo, and no bottlenecks in production. Executives say that the STAAR process is expensive, with material costs of at least $50 per Collamer "button" going into the lens and with high levels of waste, so increased production should lead to higher raw materials and work in process costs.

Considering the very steep ramp up in sales, and the manufacturing time of one to two months, work in process has barely budged during the last four years.

Chart 4. STAAR Inventory Components (FIFO) Vs Cost of Sales

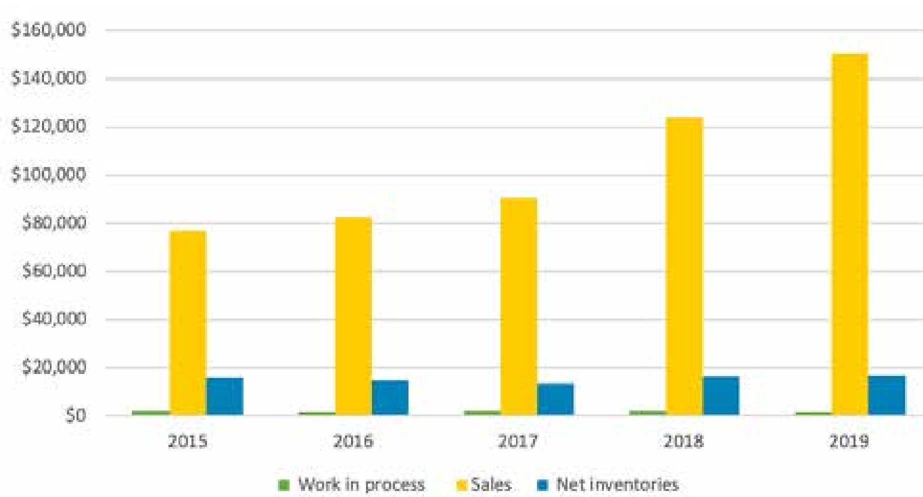


Source: Company reports

The company did report a sharp rise in works in process in Q2, but raw materials declined, and finished inventory was flat.

A weird stasis has long applied to inventories.

Chart 5. STAAR Sales vs Inventories and Works in Process



Source: Company reports

This flat pattern is remarkable, because in several conversations with production executives at STAAR, we have learned that the lens-production process takes about six weeks start to finish and requires a lengthy period of baking the lenses. Rapid growth in production, therefore, would necessarily entail a build-up in works in process.

STAAR formers have told us that they have not seen the increase in manufacturing activity that would support the reported 41% sales growth. No one, including former managers who worked within STAAR's manufacturing facility in Monrovia, can say what the unit production volume is.

STAAR's secret sauce is its own patented raw material, a bio-compatible mix called Collamer. The material is produced in a facility in Aliso Viejo, California. This facility employs about 20 people, according to our interviews, and has not expanded either equipment or personnel in two decades. Although STAAR is adding to its production facilities in both California and Switzerland, no additions are planned in Aliso Viejo.

Taxes

STAAR's cash taxes have remained puzzlingly flat over the last five years despite the company's move from losses to profits and a near tripling of profit in 2019. We consulted with tax specialists in Switzerland and the U.K., but they could not think of a reason why STAAR's cash taxes would not have risen.

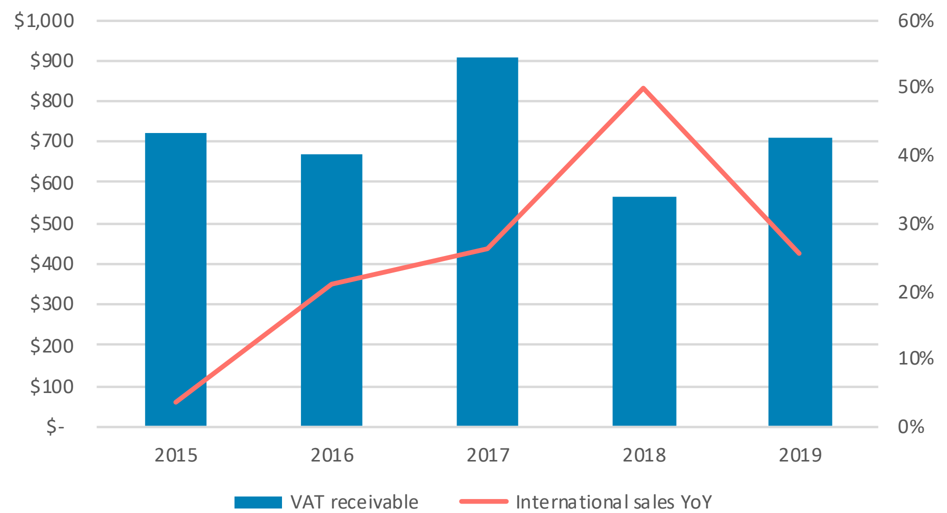
Table 4. Cash Taxes and Net Profit (,000 USD)

	2017	2018	2019
Cash taxes paid	$881	$635	$792
Net income	$(2,139)	$4,968	$14,048

Source: Company filings

VAT: The company has reported no growth in VAT receivable over five years despite very significant growth in sales in international markets where VAT returns are accrued. VAT receivable declined from $724,000 in 2015 to $713,000 in 2019 even though international sales had grown over that period by 188%.

Chart 6. VAT Receivable ($,000) and Growth in International Sales YoY



Source: Company reports

Return volumes fall short

We learned in interviews that doctors order duplicate lenses in between 30-100% of surgeries. They almost always return one pair unused. Yet we counted 33 lenses returned each month during the busy season from a distributor who claims to be selling 24,000 per year. With that volume, the distributor should be returning at least 600 lenses per month.

Inventory levels as reported by distributors are well below what would be required to support 138,000-150,000 annual lens sales in China. All the Tier 2 distributors together told us they had about 1,000 lenses in inventory, and Lansheng formers told us that company generally holds about 1,500 lenses. Distributors told us that hospitals do not hold inventory. A few Aier hospitals hold some inventory, but interviewees said those inventory levels were in the hundreds.

Comparables

The Hong Kong-listed company EuroEyes International Eye Clinic Limited (1846 HK), which operates eye clinics in China and is a shareholder as well as a client of STAAR's, reported 6.8% growth in 2019 and partly blamed

The Group's revenue in the PRC for year ended 31 December 2019 increased by 6.8% as compared to the year ended 31 December 2018. The growth rate of the Group's business in the PRC was relatively slow during the year ended 31 December 2019, which was primarily due to the fact that the Group's marketing strategies in relation to refractive laser surgery and phakic lens (ICL) surgery have not met expectations. The Group immediately took action to improve

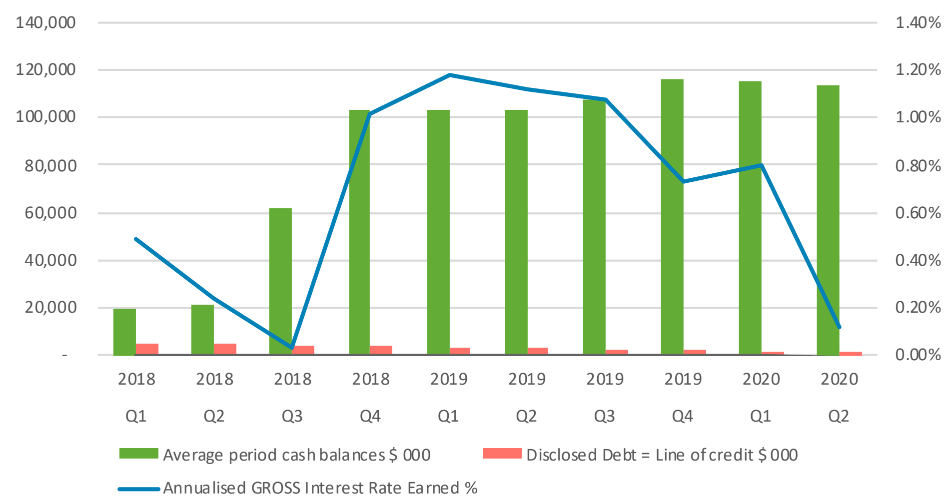
Source: Euroeyes 2019 Annual Report page 9

ICL sales for slow growth. This contrasts with STAAR's assertion that China's market is in hyper growth.

Cash

STAAR's Q2 report showed that the company earned almost no interest on its large cash balance of $116 mln—just $20,000, versus $216,000 in Q1 despite holding more cash. This is a net number, but debt is tiny, at $1.3 mln. The company in May 2020 issued a shelf offering, which is odd, since STAAR is sitting on more than 5x as much cash as it ever had prior to the secondary offering in 2018. We are hesitant to accuse any company of misleading investors about cash balances, but this is not right.

Chart 7. STAAR Cash Balances and Debt vs Annualized Gross Interest Rate



Source: Company reports

Who is Lansheng?

Curiously, STAAR reports a "hybrid distribution" model in China and yet 100% of China sales are attributed to its distributor, Lansheng.

The chairman of Lansheng, Zhang Jian, bought the medical-equipment piece of a state-owned enterprise in 2008. At that time, STAAR had just entered China through a distribution agreement with a company called Hangzhou Guochang Trade. The Hangzhou company brought sales from from $2.9 mln in 2009 to $8.4 mln in 2012. Then STAAR took back distribution. In Q4 2015, STAAR gave up on doing direct sales and handed import and distribution to Lansheng. In the same quarter, STAAR signed a "strategic cooperation" with Aier.

Table 5. Sales to Lansheng

Fiscal Year	Net Sales ($, in thousands)	Net Sales as Percentage of Consolidated Net Sales
2013	7,191	10.0%
2014	7,990	10.7%
2015	11,851	15.4%
2016	16,025	19.4%
2017	23,881	26.4%
2018	46,070	37.2%
2019	64,820	43.2%

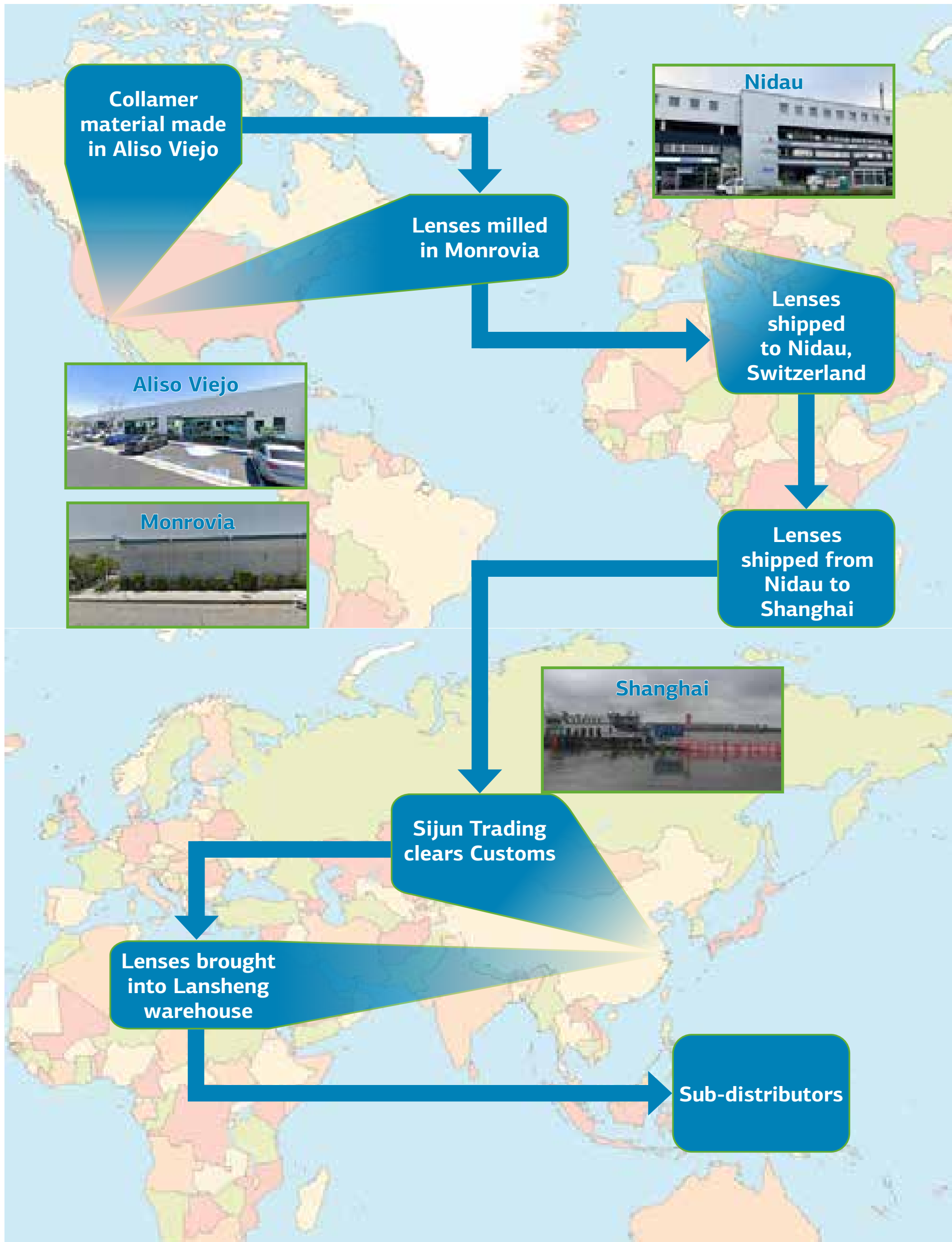
Source: STAAR 10Ks

Shortly after signing with STAAR, Zhang Jian spirited the STAAR distribution business into a separate company registered in the British Virgin Islands. He used that BVI, called Visiontec, to establish a Shanghai shadow company whose English name is the same as Lansheng's. Although the two Lanshengs are owned by the same person, they are not the same company, but STAAR has never made a new disclosure.

BVI company shareholder lists are confidential. Creating a shadow company with offshore ownership could enable Lansheng owners to engage in offshore currency and share transactions.

Top left: The Lansheng office in Shanghai. Top right and below: Lansheng maintains a registered address at the location pictured in the following two photos above, on the remote Chongming Island in Shanghai. Chongming offers deep discounts to the Value-Added Tax and income tax for companies that run their accounts through the district. | Photo by researcher April 2019.

Chart 8. Product Flow



Source: J Capital

* A Lansheng executive recently established a company called Sijun Trading, which imports the lenses from STAAR in Switzerland, according to our interviews. Lansheng then purchases the lenses from Silun.

Ways and means

There are several strategies STAAR appears to use to balance out overstated revenue and profit. One strategy is an inflated marketing budget. Another is R&D. We believe STAAR's R&D expenditure, $25.3 mln in 2019, is dramatically overstated. After interviews with former STAAR executives throughout the research and clinical operations and an estimate of the cost of the current clinical trial, we believe that actual spending on R&D may be around $5 mln. Another $3.2 mln is recorded in R&D as stock-based compensation expense. We think more than $15 mln could simply be invented and another way for the company to reconcile inflated sales.

On the R&D budget, we conducted interviews with two highly placed former R&D executives and with two other former employees working in R&D at STAAR. They estimated total internal spending on R&D at less than $5 mln. As for how much R&D has been contracted out, one of the executives said: "I would say none."

That leaves clinical trials to drive budgets, but the costs there also do not approach the more-than $20 mln booked annually. We walked through the costs with an R&D executive at a competing company who runs trials. This executive estimated that the biggest cost for trials consists of payments to surgeons and agreed with our high-end estimate of $20,000 per patient for surgery a follow-up, plus a $100 payment to the patient.

"To run a clinical study of the type the FDA would require could be $1-2 million a year and could be $2-3 million a year plus some follow-up," one former executive told us.

Remediation for the quality problems identified by the FDA in 2014 would have been included in the R&D budget and could have cost up to $3 mln a year between 2014 and 2018 on the high end, according to a former executive.

STAAR's biggest trial, seeking approval of the EVO lens in the U.S., is recruiting 333 subjects. We estimate that fees to surgeons and patients and management costs over a two-year period for this trial might be roughly $10 mln.

The table below displays all the clinical trials that STAAR has reported to clinicaltrials.gov since 2010.

Chart 6. STAAR Clinical Trials

Title	Status	Year Completed	Estimated enrollment	Locations
Prospective Comparative Study of Refractive Outcome of STAAR and Alcon Toric Intraocular Lenses	Completed	2010	100	Singapore, 1 location
Rotational Stability After Nanoflex Collamer Toric Intraocular Lens Implantation in Astigmatic Patients	Unknown status	2017	60	Italy, 1 location

Title	Status	Year Completed	Estimated enrollment	Locations
Randomized, Prospective Comparison of the Outcome of Toric Implantable Contact Lens (TICL) and Q-LASIK for the Correction of Myopia With Astigmatism	Unknown status	2008	30	China, 1 location
Clinical Performance of a Phakic Intraocular Lens (IOL)	Completed	2019	41	Belgium, Spain: 5 locations
Rotational Stability of V4C Toric Implantable Contact Lenses After On Axis Implantation Measured With OPD Scan 3	Unknown status	2018	75	Korea, 1 location
Endothelial Cell Loss After Penetrating Keratoplasty	Completed	2020	8	Egypt, 1 location
Multicenter Clinical Trial of a Phakic Implantable Collamer Lens (ICL)	Recruiting	2023	333	U.S., 14 locations
Comparative Analysis of the Visual Performance After TICL Implantation in Patients With Stable Keratoconus	Unknown status	2016	24	Tehran, Iran, 1 location
Prospective Evaluation of Near and Intermediate Visual Outcomes With Monofocal Intraocular Lenses: The Mast Study	Unknown status	2012	200	U.S., 1 location

Source: https://clinicaltrials.gov/ct2/home

Note the trial in Iran, a sanctioned area for U.S. companies. Although Clinicaltrials.gov shows 1,061 trials in Iran, the STAAR trial is the only one we could find sponsored by a U.S. company.

Lansheng formers estimated 2,000-3,000 lenses returned per year. At Lansheng's price, 2,500 returned lenses would be valued at about $1.2 mln.

Suspicious H1 volumes

Asia was gut punched by Covid-19, but STAAR reported growth. As usual, the company relied on China for the bit of good news it had to offer. In Q2, China distributor Lansheng accounted for 53% of sales and 57% of trade receivables. For the first half, STAAR said that Chinese unit sales rose by 7% and revenue declined by 2.7%, suggesting sharp discounts. In fact, several eye clinics told us that they were discounting ICL surgery, usually by about 15%.

But we interviewed 19 doctors, distributors, and marketing platforms that promote eye surgery. They said that the number of ICL procedures in China from January through June had declined by around 50-60%. Chinese clinics were closed for at least two months, sometimes more.

In May, we spoke with a Lansheng former who is in regular touch with former colleagues. This former executive estimated that Q1 sales were down 30% YoY in terms of volume and that Q2 would be more or less flat with Q2 2019.

Hospitals echoed this decline. “We did not perform any surgeries in April through June,” said a medical assistant at a large public hospital in Chengdu.

“In the second quarter, our ICL procedures were 60% of what they were last year,” said an eye surgeon in Lanzhou.

A doctor in Beijing told us that elective procedures at his hospital were down by at least 50% in May due to quarantine rules for patients coming from outside the city, while additionally, patients without urgent medical conditions were reluctant to go to hospitals. A current Lansheng employee estimated that Q1 sales had dropped by at least one-third.

“In Q1 this year, we sold about 1,000 lenses—that’s a drop of more than 50%,” a Beijing-based distributor told us.

“This year from January through April we really didn’t do any [ICL surgeries]” an eye surgeon at a major Beijing hospital told us. In 2019, this hospital saw 7% growth in ICLs.

If the growth that STAAR reported came from packing channels with inventory, the inventory is not with Lansheng. Inquiries with Lansheng and STAAR employees indicated that Lansheng in H1 was carrying substantially less than its usual inventory because of concerns that the coronavirus would make the lenses unsaleable. A Lansheng former also said that STAAR was worried that receivables could go unpaid.

Lansheng represents 100% of sales in China. If both sales and inventory were down, it is impossible that China sales grew.

The coming decline

In the Q2 call, STAAR offered a rosy outlook, saying that Q3 would see at least 20% sequential growth and double-digit growth year on year. Mason said that China in July had “on several days, hit implantation records.”

Our hospital interviews indicate that July did have much higher volumes but that these were make-up volumes for May-June.

One of the largest Aier hospitals, occupying four floors of a shopping center in Beijing, told us that ICL surgeries were down 33-50% "during the pandemic" but had recovered in July to about the same level as July 2019. Another clinic said that volumes had doubled over July 2019 but had been sharply down in the first half.

"In May, the hospitals started gradually to get back to normal, and this led to explosive growth in July," a Lansheng Tier 2 distributor told us.

"In April through June, we didn't do any surgeries," a hospital in Chengdu told us. "In July, numbers grew 20% compared with July last year."

We do not believe the summer months will make up for lost business in the first half.

We spoke with 19 eye hospitals and distributors that purchase from STAAR about their sales volumes in 2020 versus 2019. Six refused to disclose sales volumes. Two said their businesses had returned to normal volumes by May. The remaining 11 were seeing dramatic declines in implant surgeries and expected the full year would be significantly lower than last year.

Chart 7. Interviews

Date	Institution	Q1 Compared With Q1 2019?	Q2 2020 Yoy?	How Was H1 Compared With The Same Period In 2019?	What Kind Of Growth Or Decline Do You Expect For The Full Year 2020?
7/14/20	Changchun, Jilin lens distributor	1 lens in 2020 compared with 20 in 2019.	0 compared with 40 in Q2 2019.	In H1 2019 we implanted about 80 lenses. In 2020 H1 just 1.	Down 50%
7/13/20	Sichuan hospital	None in Q1 2020. 20 in Q1 2019.	0 compared with 20 in Q2 2019	Around 50 surgeries in H1 2019. None in 2020.	Don't know
7/13/20	Zigong, Sichuan hospital	50% down	About the same	Down 50%	30-50% lower than our target
7/13/20	Chongqing hospital	Poor	About the same	Down 10%	Hard to say, we'll be lucky if we sell 100 lenses.
7/13/20	Guizhou hospital	About the same	Q2 was down by about a dozen surgeries.	down	Down by around 25%
7/13/20	Guiyang, Guizhou hospital	Down 50%	down about 30%	down 30%	This year due to the virus we sold 400-500 lenses, about the same was last year.

Date	Institution	Q1 Compared With Q1 2019?	Q2 2020 Yoy?	How Was H1 Compared With The Same Period In 2019?	What Kind Of Growth Or Decline Do You Expect For The Full Year 2020?
7/13/20	Lanzhou, Gansu hospital	0 compared with 4 lenses lest year Q1.	Down about 50%	Really poor	This isn't a core offering for us. Last year we sold about 20 lenses. This year might be about the same.
7/13/20	Xian, Shaanxi eye clinic	About a dozen lenses compared with 50-60 last year Q1.	Down a little bit	Much worse than 2019	We just hope we can do the same as last year.
7/13/20	Beijing lens distributor	0	2 lenses 2020 H1 versus 20 in 2019 H1.	Two lenses in H1 2020 versus 20 in H1 2019.	We expect to do fewer than 10 lenses this year. We did 30 last year.
7/14/20	Beijing eye clinic	About the same	About the same	Same	We did 300-400 lenses last year. We expect this year to improve. In April and May the volume returned to normal.

Source: J Capital

We visited nine eye hospitals in Beijing and Shanghai in August to check-on business. We did not find anyone lining up out the doors, though the hospitals told us volumes were back more or less to normal.

Waiting area at Shanghai Aier. | Photo by researcher August 2020.

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The Aier Intech Eye Hospital in Beijing, a large buyer of ICLs. Staff told us that volumes had been down 30-50% through June but in July were at normal levels. | Photo by J Capital August 2020.

Waiting area at Shanghai Purui | Photo by researcher August 2020.

The C-Mer (Beijing) Dennis Lam Eye Hospital told us that volumes had come back to normal in July but without many ICL surgeries. The hospital is offering discounts of 20-25%. | Photo by J Capital August 2020.

Audit

Technically, STAAR has a very small operation in China, relying on Lansheng to do sales, and does not need to be audited in China. But STAAR derives 43% of its revenue from the Chinese market and has a large marketing budget that is presumably dedicated to China.

Interestingly, our interviews showed that STAAR does not have an ERP in place; its IT system consists only of the Online Calculation and Ordering System (OCOS)[6] used by doctors to choose the right size and magnification for a patient's lens. The actual ordering is done in batches by emailed Excels and in phone calls. Lansheng says that they order the commonly used magnifications in batches rather than ordering specific lenses for specific procedures. Lansheng built its own inventory management system in 2018, but its sub-distributors generally use a manual system for inventory management.

6 https://ocos.staarag.ch/landing/

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Blurring the picture for investors

STAAR has a pattern of lying to investors and regulators. The company paid out $10.7 mln to settle two separate class-action lawsuits over a decade: both of the lawsuits alleged that STAAR hid from investors deficiencies found by the FDA in STAAR's management processes.[7] Court and FDA records show that the company got trial subjects to backdate consent forms, ignored counter indications, "lost" documentation, could not find (or refused to disclose) the password to the ordering system. In one lawsuit, a STAAR executive said the company instructed her to provide false information to the FDA.[8] Like other the lawsuits against the company, this was settled out of court, and details are unavailable. But we spoke with an employee who worked in quality control until mid-2019, who told us that the company continues to "hide things for audits."

The company's lawsuits could fill their own 10K:

- November 2000: Former employee Kirtida Patel sued the company, alleging that management had instructed her to withhold information from the FDA and had lied to the FDA.
- December 2000: A shareholder derivative suit alleged self-dealing and waste of assets by directors.
- October 2001: Novastaar Investments, LLC sued to win the right to inspect records pertaining to $6 mln in loans to directors, service contracts paid to companies owned by directors, $24 mln in asset write-offs, defaulted loans, and other transactions.
- June 2007: the company was warned by the FDA for failing to respond to adverse events from clinical trials. The FDA advised that STAAR hire an independent auditor. The company declined to take that step. The FDA later told STAAR that its response was "inadequate."

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7 $7 mln 2018 settlement: https://www.massdevice.com/staar-surgical-settles-class-action-suit-7m/. $3.7 mln settlement in 2006: http://securities.stanford.edu/filings-documents/1032/STAA04-01/2006526_r01x_04CV08007.pdf Another suit is being organized around poor disclosure of FDA action in May 2019: https://www.globenewswire.com/news-release/2019/06/25/1874172/0/en/SHAREHOLDER-ALERT-Pomerantz-Law-Firm-Investigates-Claims-On-Behalf-of-Investors-of-STAAR-Surgical-Company-STAA.html

8 See STAAR annual report 2000 page 17, "Kirtida ("Kirty") Patel v. STAAR Surgical Company, Orange County Superior Court; Case No. OOCC13556." - 4 -

- February 2015: The FDA issued a letter containing 10 "observations" focusing on the need for improved procedures, processes and documentation and broader environmental monitoring. A quality inspector we spoke with who worked at the Monrovia facility told us that in late 2019, procedures will have not been improved.

- 2015: Two activist shareholders demanded changes to the board to address chronic losses and what they said was the company's inability to exploit growth opportunities in China. No changes were made, but STAAR appointed Lansheng as its distributor in China and growth accelerated.

- June 2016: Kevin Forestal filed a stockholder derivative complaint claiming that STAAR disseminated misleading statements to investors and engaged in unjust enrichment.

Executive compensation

We find company compensation to be out of proportion to results. Despite almost unbroken losses through 2017, top executives took option awards worth $9.7 mln in 2016-19 and total compensation averaging $1 mln per year.

Lansheng enabled STAAR to end a history of losses that had been broken just twice since 1995, and the black ink helped double compensation for CEO Caren Mason and other members of the executive team. STAAR's targets for executive bonuses and share compensation incentivize overall revenue and profit growth (or a reduction in losses). In 2019, Mason made $3.6 mln in cash and share options, an increase of 38% over 2018 compensation of $2.6 mln

Chart 8. Calculated Total Compensation (,000 USD)

		2016	2017	2018	2019	Total
Andrews, Deborah J.	CFO	-	$1,475.	$823	$854	$3,153
Barnes, Scott D.	CMO	-	$608	$949	$1,246	$2,803
Blickensdoerfer, Hans-Martin	Sr VP	$770	$699	$1,102	$1,032	$3,604
Holliday, Keith	CTO	$635	$853,	$1,092	$1,072	$3,653
Mason, Caren L.	CEO	$1,526	$1,866	$3,627	$3,616	$9,635

Source: Capital IQ

Share compensation in 2019, $11.6 mln, was equivalent to 82% of STAAR's 2019 net income. In Q1 this year, despite losing money, STAAR still issued $2.9 mln in new stock-based compensation.

Management has impeccable timing when it comes to share sales.

- On June 14, 2018, Director William P. Wall and two other insiders were awarded shares. On August 1, the company raised guidance. On August 20, Wall sold 5,000 shares.
- Between November 14 and December 13, 2019, five insiders sold shares. On January 2, 2020, longtime investor and activist Broadwood Capital sold a block of 41,220 shares.
- On March 18-20, 2020, six insiders acquired shares. On May 6, against all Covid-19 odds, the company announced strong growth in Q1. On May 11-15, the same six insiders sold shares.

Disclaimer