STAAR SURGICAL CO
Form 8-K
August 10, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 7, 2018

STAAR Surgical Company

(Exact Name of Registrant as Specified in Charter)

Delaware	0-11634	95-3797439
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
1911 Walker Ave., Monrovia, California **(Address of Principal Executive Offices)**		91016 **(Zip Code)**

Registrant's Telephone Number, Including Area Code 626-303-7902

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

¨Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1 933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

Item 1.01. Entry into a Material Definitive Agreement.

On August 7, 2018, STAAR Surgical Company (the "Company") entered into an Underwriting Agreement with Canaccord Genuity LLC, for itself and as representative of the other several underwriters (the "Underwriters"), providing for, subject to customary closing conditions, the purchase from the Company of 1,739,000 shares of its common stock (the "Common Stock"). In addition, the Company granted the Underwriters an option (the "Option"), exercisable for 30 days after the date of the Underwriting Agreement, to purchase up to an aggregate of 260,850 additional shares of Common Stock, which was exercised in full on August 9, 2018. The closing of the offering is expected to occur on August 10, 2018, subject to customary closing conditions. The net proceeds to the Company in this offering before deducting expenses are estimated to be approximately $72,612,554.

The Underwriting Agreement contains customary representations, warranties, covenants and agreements by the Company, indemnification and other obligations of the parties, and termination provisions.

The Underwriting Agreement is filed as Exhibit 1.1 to this report, and the foregoing description is qualified in its entirety by reference to such exhibit. All shares are being sold pursuant to a shelf Registration Statement on Form S-3, File Number 333-217888 (the "Registration Statement") that was declared effective by the U.S. Securities and Exchange Commission (the "SEC") on June 9, 2017, as well as a preliminary prospectus supplement and a final prospectus supplement each dated August 7, 2018 (the "Prospectus Supplement") to the base prospectus contained in the Registration Statement. The Prospectus Supplement, which incorporates the base prospectus, is available on the SEC's website at http://www.sec.gov and is hereby incorporated into this Item 1.01 by this reference.

Item 8.01. Other Events.

Unless the context otherwise requires, the terms "we," "our" or "us" and "STAAR" refer to STAAR Surgical Company and it subsidiaries. References to our "common stock" refer to the common stock of STAAR Surgical Company.

RISK FACTORS

Investment in our securities involves a high degree of risk. Investors should carefully consider the risks described below, as well as the risks described in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and all other information included or incorporated by reference in this prospectus, before making a decision to invest in our common stock. These risks are not the only ones we face. These risks and

uncertainties, as well as other risks that we cannot foresee at this time, have the potential to affect our business, financial condition, results of operations, cash flows, strategies and prospects in a material and adverse manner. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment. This prospectus supplement, the accompanying prospectus and the documents incorporated by reference also contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those anticipated or implied in these forward-looking statements because of factors beyond our control, including the risks faced by us described below and in the documents incorporated herein by reference.

Risks Related to Our Business

We have a history of losses that may continue in the future.

We have reported losses in four of the past five years. Our near-term profitability is challenged by the competitive nature of our industry, our continued investment in operations, and the other risks to our business detailed herein. There can be no guarantee that we will achieve growth, or profitability, in the near term, or at all. If unexpected events increase our expenses or harm the performance of our business we may need to seek additional financing. We may also identify opportunities to expand our business that require additional financing. Should we need additional working capital, our ability to raise capital through sales of equity securities depends on general market conditions and the demand for our common stock. We may be unable to raise adequate, if any, capital through sales of equity securities, and if our stock has a low market price at the time of such sales our existing stockholders could experience economic dilution. We may also have difficulty obtaining debt financing on acceptable terms, if at all, or renewing existing debt facilities. If additional funds are raised through the incurrence of debt, we will incur debt servicing costs and may become subject to restrictive financial and other covenants. An inability to secure additional financing if it is needed in the future could require us to forego opportunities for expansion, or could adversely affect our operations and financial position. Also, if we cannot continue to generate positive cash flow from operations, we may have to reduce our costs which could materially and adversely affect our ability to execute our operations and expand our business.

FDA compliance issues may adversely impact our operations.

Quality system and other deficiencies observed at certain of our facilities during inspections have led to FDA Warning Letters, FDA Form 483s and delays in product approvals until the FDA determines we resolved its concerns. For example, on May 21, 2014, we received a Warning Letter from the FDA citing alleged violations of the current Good Manufacturing Practices (“cGMP”) requirements of the Quality System Regulation (“QSR”) identified by the FDA during an inspection of the Company’s manufacturing facility in Monrovia, California in early 2014. We manufacture most of our products at the Monrovia facility. On June 20, 2018, we announced receipt of a letter from the U.S. Food and Drug Administration lifting the Warning Letter, which reopens the regulatory pathway for us to obtain U.S. approval for products, however, obtaining product approval remains a costly and lengthy process and it is too soon to tell whether the lifting of the Warning Letter will result in regulatory approvals, expanded U.S. sales or the timing of such developments. For example, there is no assurance that the lifting of the Warning Letter will result in approval of our supplemental premarket approval (“PMA”) from the FDA for the Toric ICL.

Despite the lifting of the Warning Letter, the FDA retains the authority to impose additional regulatory action on STAAR. If we fail to demonstrate continued compliance we could be subject to fines, injunctions, Warning Letters, consent decrees, prosecution, civil money penalties, criminal penalties, costs of repairs and replacements, refunds, recalls or seizures of products, total or partial suspension of production and marketing, the FDA's refusal to grant future premarket approvals, and/or withdrawals or suspensions of approvals or clearance for current products. Any such further action might severely impair our ability to do business and financial condition.

Our management expects to devote significant resources and attention to our quality systems and compliance with QSR and other regulatory requirements for the foreseeable future as part of the ordinary course of business. We cannot ensure that our efforts will be successful and failure to achieve or maintain compliance may materially and adversely impact our business and operations, as noted above.

We rely and depend on independent distributors in international markets.

Except for the U.S., Japan, Spain, Germany, Canada, the U.K. and Singapore, we sell our products through independent distributors who generally control the importation and marketing of our product within their territories. We generally grant exclusive rights to these distributors and rely on them to understand local market conditions, to diligently sell our products and to comply with local laws and regulations. Our agreements with distributors and local laws can make it difficult for us to quickly change from a distributor who we feel is underperforming. If we do terminate an independent distributor, we may lose customers who have been dealing with that distributor, and may be required to compensate the distributor for termination. Because these distributors are independent, it may be difficult for us to detect failures in our distributors' performance or compliance. Actions by independent distributors could result in declining sales in that territory, harm to the reputation of our company or our products, or legal liability. For example, if Shanghai Langsheng, which accounted for more than 26% of our fiscal 2017 consolidated net sales, and more than 40% of net sales in our fiscal quarter ended June 29, 2018, ceased to serve as our distributor, or significantly underperformed our expectations, we may experience a substantial reduction in sales.

Unfavorable economic conditions or negative publicity concerning complications of laser eye surgery could hurt sales of our refractive products.

During our fiscal quarter ended June 29, 2018, approximately 80% of our revenue was derived from ICL lenses used in refractive procedures. Refractive surgery is an elective procedure generally not covered by health insurance. Patients must pay for the procedure, frequently through installment financing arrangements with third parties. They can defer the choice to have refractive surgery if they lack the disposable income to pay for it or do not feel their income is secure. Economic stagnation, lack of consumer confidence or new recessions in any of our larger markets could slow ICL sales growth or, if severe, cause declines in sales. Because the ICL is our best selling and highest gross margin product, restricted growth or a decline in its sales could materially harm our business.

We believe that negative publicity in the past regarding the potential complications of refractive surgery and potential patient dissatisfaction, in particular because of LASIK and other corneal laser-based procedures, decreased patient interest in LASIK as well as all other refractive procedures. Depending on the nature and severity of any future negative publicity about refractive surgery, the growth of ICL sales could be limited or sales could decline due to decreased patient interest in all refractive surgery.

Disruptions in our supply chain or failure to adequately forecast product demand could result in significant delays or lost sales.

The loss of a material supplier could significantly disrupt our business. In some cases, we obtain components used in certain of our products from single sources. If we experience difficulties acquiring sufficient quantities of required materials or products from our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's QSR, other applicable laws, or STAAR's requirements, then qualifying and obtaining the required regulatory approvals to use alternative suppliers may be a lengthy and uncertain process during which production could be delayed and we could lose sales.

Our sources of supply for raw materials may be threatened by shortages and other market forces, by natural disasters, by the supplier's failure to maintain adequate quality or a recall initiated by the supplier. Even when substitute suppliers are available, the need to verify the substitute supplier's regulatory compliance and the quality standards of the replacement material could significantly delay production and materially reduce our sales.

In particular, we manufacture the proprietary collagen-based raw material used in our ICLs and IOLs internally. If the supply of these collagen-based raw materials is disrupted it could result in our inability to manufacture those products and would have a material adverse effect on STAAR. The loss of our external supply source for silicone material, polymer for injectors or acrylic lenses could also cause us material harm.

Further, any failure by us to forecast demand for or to maintain an adequate supply of, raw material and finished product could result in an interruption in the supply of certain products and a decline in the sales of that product. If our suppliers or we are unable or our suppliers are unwilling to meet our manufacturing requirements, we may not be able to produce enough materials or products in a timely manner, which could cause a decline in our sales.

Because our business is global our sales and profits may fluctuate or decline in response to changes in foreign currency exchange rates and other international risks.

Activities outside the U.S. accounted for approximately 91% of our total sales during 2017. Foreign currency fluctuations could result in volatility of our revenue. The results of operations and the financial position of our Japanese subsidiary are reported in Japanese yen and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. In addition, we are exposed to transaction risk because we incur some of our sales and expenses currencies other than the U.S. dollar. Our most significant currency exposures are to the Japanese yen, the euro, and the Swiss franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. The strengthening of the U.S. dollar would likely negatively impact our results. We price some of our products in U.S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation in emerging markets could also make our products more expensive and increase the credit risks to which we are exposed. Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability, and stock price.

Economic, social, and political conditions, laws, practices, and local customs vary widely among the countries in which we sell our products. Our operations outside of the U.S. face a number of risks and potential costs, including, enjoying less stringent protection of intellectual property, and facing economic, political, and social uncertainty in some countries, especially in emerging markets. For example, sales in certain Asian and developing markets may result in lower margins and higher exposure to intellectual property infringement or counterfeits. Further, trade disputes between the United States and its significant trading partners, including China, may adversely affect our sales, including as a result of the imposition of tariffs or other barriers or restrictions on trade, or increase our costs. In addition, the institution of trade tariffs both globally and between the U.S. and China specifically could negatively impact the overall economic condition in our markets, including China, which could have a negative effect on our sales. Also, we are exposed to credit and collectability risk on our trade receivables with customers in certain international markets. There can be no assurance we can effectively limit our credit risk and avoid losses and our ability to transfer foreign earnings to the U.S. may be subject to taxes or restricted or result in incurring substantial costs. Our continued success as a global company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries where we do business. These and other risks may have a material adverse effect on our operations in any particular country and on our business, financial condition, and results of operations as a whole.

We may not be able to fully use our recorded tax loss carryforwards.

We have accumulated approximately $132.5 million of U.S. federal tax net operating loss carryforwards as of December 29, 2017, which can be used to offset taxable income in future quarters if our U.S. operations become profitable. If unused, these tax loss carryforwards will begin to expire between 2020 and 2037. At this time, we do not believe our U.S. operations will generate sufficient profitability during the near term to enable us to use the totality of our net operating loss carryforwards before they expire. Also, currently if we generate profits on a consolidated basis, those profits are expected to be primarily generated outside the U.S. and subject to income taxes, which cannot be offset with U.S. loss carryforwards. If profits occur in the U.S. this will enable us to begin using our tax loss carryforwards in the U.S., but changes in tax laws could prevent or hinder us from realizing the full benefits of the U.S. loss carryforwards. Our ability to utilize any future net operating losses may also be limited by the recently enacted legislation commonly known as the Tax Cuts and Jobs Act, or the Tax Act. Under the Tax Act, the amount of post-2017 net operating losses that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year. In addition, the Tax Act generally eliminates the ability to carry back any net operating loss to prior taxable years, while allowing post-2017 unused net operating losses to be carried forward indefinitely. Due to these changes under the Tax Act, we may not be able to realize a tax benefit from the use of our net operating losses, whether or not we generate profits in future years. Moreover, if we were to experience a significant change in ownership, Internal Revenue Code Section 382 may restrict the future utilization of our tax loss carryforwards even if our U.S. operations generate significant profits.

We are vulnerable to any loss of use of our principal manufacturing facility.

We manufacture most of our products at a single facility in Monrovia, California, which is the sole manufacturing facility for our ICLs and IOLs. All or a portion of the Monrovia facility could suffer catastrophic loss due to fire, flood, earthquake, terrorism or other natural or man-made disasters, including manufacturing challenges such as equipment failure. Developing a second manufacturing site would require significant expense for personnel and equipment and a long period to obtain regulatory approvals. Our California and Japanese facilities are in areas where earthquakes could cause catastrophic loss.

In our major markets, regulatory approval to manufacture materials and sell our products is generally limited to the current manufacturing site, and changing the site requires applications to and approval from regulatory bodies prior to commercialization. To satisfy our own quality standards as well as regulations, we must follow strict protocols to confirm that products and materials made at a new site are equivalent to those made at the currently approved site. Even minor changes in equipment, supplies or processes require validation. Unanticipated delays or difficulties in manufacturing a transferred process or materials could interrupt our supply of products. Any sustained interruption in supply could cause us to lose market share and harm our business, financial condition, and results of operations.

If any or a portion of our facilities were to experience a catastrophic loss, or if one of our facilities is found not to be in compliance with regulatory requirements, it could disrupt our operations, delay production and shipments, delay or reduce sales and revenue and result in large expenses to repair or replace the facility, as well as lost customers or sales. Our insurance for property damage and business interruption may not cover any particular loss, or, if covered, be sufficient. We do not carry insurance or reserve funds for interruptions or potential losses arising from earthquakes or terrorism.

We depend on key employees.

We depend on the continued service of our senior management and other key employees. The loss of a key employee could hurt our business. It could be particularly detrimental if any key employee or employees went to work for a competitor. Also, our future success depends on our ability to identify, attract, train, motivate and retain other highly skilled personnel. Failure to do so may adversely affect our results. We do not maintain insurance policies to cover the cost of replacing the services of any of our key employees who may unexpectedly die or become disabled.

We compete with much larger companies and low-cost Asian manufacturers.

Our competitors, including Novartis (formerly Alcon), Johnson & Johnson (formerly Abbott Medical Optics, or AMO) and Valeant (formerly Bausch & Lomb), have much greater financial, technical, marketing and distribution resources and brand name recognition than we do and some of them have large international markets for a full suite of ophthalmic products. Their greater resources for research, development and marketing, and their greater capacity to offer comprehensive products and equipment to providers, makes for intense competition. Over the past several years, we have lost market share in IOL sales to some of our competitors. In addition, competitors from Asia are beginning to appear in some markets with their low-cost version of an implantable contact lens, which competes with our ICL.

Non-compliance with anti-corruption laws could lead to penalties or harm our reputation.

We are subject to anti-corruption laws in the jurisdictions in which we operate, including the U.S. Foreign Corrupt Practices Act ("FCPA"). Any failure to comply with these laws, even if inadvertent, could result in significant penalties or otherwise harm our reputation, business, financial condition, and results of operations. Our reliance on foreign subsidiaries and independent distributors demands vigilance in maintaining our policy against participation in corrupt activity. In many of our markets outside the U.S., doctors and hospital administrators may be deemed government officials. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with such individuals.

We could experience losses due to product liability claims.

We have been subject to product liability claims in the past and may experience such claims in the future. Product liability claims against us may not be covered, may exceed the coverage limits of our insurance policies or cause us to record a loss in excess of our deductible. A product liability claim that exceeds our insurance coverage could materially harm our business, financial condition, and results of operations. Even if an insurance policy covers a product liability loss, we must generally pay for losses until they reach the level of the policy's stated deductible or retention amount after which the insurer begins paying. The payment of retentions or deductibles for a significant number of claims could have a material adverse effect on our business, financial condition, and results of operations.

Any product liability claim would divert managerial and financial resources and could harm our reputation with customers. We cannot assure investors that we will not have product liability claims in the future or that such claims would not have a material adverse effect on our business.

Our defined benefit pension plans are currently underfunded and we may be subject to significant increases in pension benefit obligations under those pension plans.

We sponsor two defined benefit pension plans through our wholly owned Swiss and Japanese subsidiaries, which we refer to as the "Swiss Plan" and the "Japan Plan," respectively. Both plans are underfunded and may require significant cash payments. We determine our pension benefit obligations and funding status using many assumptions. If the investment performance does not meet our expectations, or if other actuarial assumptions are modified, or not realized, we may be required to contribute more than we currently expect and increase our future pension benefit obligations to be funded from our operations. Our pension plans taken together are underfunded by approximately $4.7 million ($1.4 million for the Japan Plan and $3.3 million for the Swiss Plan) as of December 29, 2017. If our cash flow from operations is insufficient to fund our worldwide pension obligations, as well as other cash requirements, we may be materially and adversely harmed and have to seek additional capital.

Our activities involve hazardous materials, emissions, and use of an irradiator and may subject us to environmental liability.

Our manufacturing, research and development activities involve the use of hazardous materials and equipment and use of an irradiator. Federal, state and local laws and regulations govern the use, manufacturing, storage, handling and disposal of these materials and certain waste products in the places where we have operations. We cannot eliminate the risk of accidental contamination or injury from these materials and equipment. Remedial environmental actions could require us to incur substantial unexpected costs, which could materially and adversely affect our financial condition and results of operations. If we were involved in an environmental accident or found to be in substantial non-compliance with applicable environmental laws, it could harm our reputation, and we could be held liable for damages or penalized with fines.

Data corruption, cyber-based attacks or network security breaches and noncompliance with data protection regulations could negatively impact our operations.

We depend on information technology networks and our information technology infrastructure for electronic communications among our locations around the world and between our personnel and our subsidiaries, customers, and suppliers. The integrity and protection of our customer, vendor, supplier, employee, and other Company data, is an important part of our business. Addressing applicable security and privacy regulations may increase our operating costs or adversely affect our business operations.

Unauthorized parties may also gain access to our systems or facilities. Security breaches could disrupt our operations, and result in lost or misappropriated information. Despite the security measures we have in place, our facilities and systems, and those of our suppliers, distributors and customers with whom we do business, may be vulnerable to security breaches, cyber-attacks, or other similar events. Any security breach of Company information could have a material adverse effect on our business, results of operations and financial condition. Also, certain of our information technology systems are not redundant, and our disaster recovery planning is not sufficient for every eventuality. Despite any precautions we may take, such events could harm our reputation and financial results.

We are subject to various data protection regulations in different jurisdictions, including the General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR). We have made and continue to engage in compliance efforts to satisfy these regulations, however, we may be unsuccessful in complying with applicable requirements, and may be at risk of enforcement actions and/or subject to fines, including those imposed by a data protection authority. As a result, we may incur substantial expense in complying with data protection regulations and may be distracted from other aspects of our business.

The increased use of social media platforms and mobile technologies presents additional risks and challenges.

New technologies are increasingly used to communicate about our products and the health conditions they are intended to treat. The use of these media poses risks to our business and requires specific attention and monitoring. For example, patients, competitors, or others may use these channels to comment on the safety or effectiveness of a product and to report an alleged adverse event. Negative posts or comments about us or our business on any social networking web site could harm our reputation. In addition, our employees may use social media tools and mobile technologies inappropriately, which may give rise to liability, or which could lead to the exposure of sensitive information. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition, and results of operations.

Acquisitions of technologies, products, and businesses could disrupt our operations, involve increased expenses and present risks not contemplated at the time of the transactions.

We may consider and, as appropriate, make acquisitions of technologies, products, and businesses that we believe are complementary to our business. Acquisitions typically entail many risks and could result in difficulties in integrating the operations, personnel, technologies, and products acquired, and mitigating the risk of unknown liabilities some of which may result in significant payments or charges to earnings.

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business, and our ability to develop and introduce new products. Actual costs and sales synergies, if achieved at all, may be lower than we expect and may take longer to achieve than we anticipate. Acquisitions may also divert management's attention from our core business. Furthermore, the products of companies we acquire may overlap with our products or those of our customers, creating conflicts with existing relationships or with other commitments that are detrimental to the integrated businesses.

If we are not able to manage growth successfully, this could adversely affect our business, financial condition, and results of operations.

If we continue to experience rapid growth, this places a significant strain on financial, operational, and managerial resources. We must continue to implement and enhance our managerial, operational and financial systems, expand our operations, and continue to recruit and train qualified personnel. There can be no assurance that our strategic and operational planning will allow us to adequately manage anticipated growth. Any inability to successfully manage growth could materially and adversely affect our business, financial condition, and results of operation.

Risks Related to the Ophthalmic Products Industry

Unless we keep pace with advances in our industry and persuade physicians to adopt our new products our sales will not grow and may decline.

Our future growth depends, in part, on our ability to timely develop products to treat diseases and disorders of the eye that are more effective, safer, or incorporate emerging technologies better than our competitors' products, and are accepted by physicians and patients. Sales of our existing products may decline rapidly if one of our competitors introduces a superior product, or if we announce a new product of our own. If we focus on research and development or technologies that do not lead to better products, more effective or advanced products could surpass our current and planned products. In addition, such product development efforts could require a significant investment of resources. If we are able to develop new products, we must manufacture these products economically and market them successfully by demonstrating to enough eye-care professionals the overall benefits of using them. If we do not timely develop new products that meet market demand or if there is insufficient demand for our new products, our sales and results of operations could be harmed.

Resources devoted to research and development may not yield new products that achieve regulatory approval or commercial success.

Development of new implantable technology, from discovery through testing and registration to initial product launch, is expensive and time-consuming. Because of the complexities and uncertainties of ophthalmic research and development, products we are developing, including those currently in development, may not complete the development process or obtain the regulatory approvals required for us to successfully market the products. Our new products, including those currently under development, may fail to become commercially successful.

We may be required to conduct extensive clinical trials to demonstrate safety and efficacy of new or enhanced products, which clinical trials are expensive, complex, can take years to complete, and have highly uncertain outcomes.

In order to further advance the development of, and ultimately receive regulatory approval to manufacture and sell, our new products or product enhancements, we may be required to conduct extensive clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or regulatory authorities in other countries. Clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of the clinical trials, and can result from concerns about safety, a lack of demonstrated efficacy, or poor study or trial design. The commencement and completion of clinical trials may be

delayed or prevented by many factors, including, but not limited to:

- an inability to timely identify and reach agreement on acceptable terms with prospective clinical trial sites and entities involved in the conduct of our clinical trials;

- failure by third-party clinical trial managers to comply with applicable regulations or protocols;
- flaws in the design of the clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- periodic amendments to clinical trial protocols to address certain variables which arise during the course of a trial;
- lack of effectiveness of our products; or
- unforeseen safety issues.

We are subject to extensive government regulation worldwide, which increases our costs and could prevent us from selling our products.

We are regulated by regional, national, state and local agencies in the U.S. as well as governmental authorities in those international countries in which we manufacture or distribute products, such as in Europe and Asia. These regulations may govern the research, development, manufacturing, and commercial activities relating to medical devices, including their design, pre-clinical and clinical testing, clearance or approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. Failure to receive necessary approvals in foreign jurisdictions on a timely basis, or at all, could harm our business and operating results. In addition, regulations and requirements for approvals can vary in each international country, which can significantly increase the costs to sell our products in these international countries.

Complying with government regulation substantially increases the cost of developing, manufacturing and selling our products.

Competing in the ophthalmic products industry requires us to introduce new or improved products and processes continuously, and to submit these to the FDA and other regulatory bodies for clearance or approval. Obtaining clearance or approval can be a long and expensive process, and clearance or approval is never certain. For example, the FDA or another country's regulatory agency, could require us to conduct an additional clinical trial prior to granting clearance or approval of a product and such clinical trial could take a long time and have substantial expense. Furthermore, there is no assurance that clearance or approval will be granted.

If a regulatory authority delays or does not grant approval of a potentially significant product, the potential sales of the product and its value to us can be substantially reduced. Even if the FDA or another regulatory agency clears or approves a product, the clearance or approval may limit the indicated patient populations or uses of the product, or may otherwise limit our ability to promote, sell and distribute the product, or may require post-marketing studies or surveillance. If we cannot obtain timely regulatory clearance or approval of our new products, or if the clearance or approval is too narrow, we will not be able to successfully market these products, which would eliminate or reduce our potential sales and earnings.

In addition, the FDA and other regulatory authorities may change their clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development, cause the loss of previously received approvals or clearances or impact our ability to modify our currently cleared products on a timely basis.

We depend on proprietary technology but our intellectual property protections may be limited.

While we rely on patents, trademarks, trade secrecy laws, contractual provisions and confidentiality procedures and copyright laws to protect the proprietary aspects of our technology, we rely more on trade secrets and know-how, which may not prevent third parties from using publicly available information to access our technology. With respect to our patents, any of them may be challenged, invalidated, circumvented or rendered unenforceable. Any of our pending patent applications may fail to result in an issued patent or fail to provide meaningful protection against competitors or competitive technology. Litigation may be necessary to enforce our intellectual property rights, and to protect or determine the validity and scope of our proprietary rights. We also challenge others' patents or patent applications from time to time. Any litigation could result in substantial expense, may reduce our profits, and may not adequately protect our intellectual property rights. In addition, we may be exposed to future litigation by third parties based on claims that our products infringe their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of claims covered by patents in our industry may involve complex legal issues that are open to dispute. Any litigation or claims against or instituted by us, whether or not successful, could result in substantial costs, divert resources and the efforts of our personnel away from daily operations, harm our reputation, result in the impairment of our intellectual property rights, limit our ability to pursue future products and/or otherwise materially adversely impact our business.

We may not successfully replace our existing products, including those that lose or have lost patent protection.

As our existing patents expire, many of which already expired over the past several years, our competitors may introduce products using the same technology. Because of this possible increase in competition, we may lose sales and/or may need to reduce our prices to maintain sales of our products, which would make them less profitable. If we fail to develop and successfully launch new products and/or obtain new patents, our sales and profits with respect to our products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products.

While we will continue developing intellectual property protections for our future products, third parties may pursue blocking patents that limit our ability to manufacture such products.

We plan to continue relying on patents, trade secrets and other intellectual property rights to protect products and technology that we may develop or employ in the future, but third parties may develop and obtain patents covering such products or technology. In such event, we may need to obtain licenses for such patents. However, we may not be able to obtain licenses on reasonable terms, if at all, which could limit our ability to manufacture our future products and operate our business.

Laws pertaining to healthcare fraud and abuse could materially adversely affect our business, financial condition, and results of operations.

We are subject to various federal, state, local and international laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment, and exclusion from participation in healthcare programs such as Medicare and Medicaid, and health programs outside the United States. These laws and regulations are wide ranging and subject to changing interpretation and application, which could restrict our sales or marketing practices. Furthermore, because many of our customers, particularly IOL customers, rely on reimbursement from Medicare, Medicaid, and other governmental programs to cover a substantial portion of their expenditures, our exclusion from such programs because of a violation of these laws could have a material adverse effect on our business, results of operations, financial condition, and cash flow.

If we recall a product, the cost and damage to our reputation could harm our business.

We have voluntarily recalled our products in the past and recalls could take place again. We may also be subject to recalls initiated by manufacturers of products we distribute. We cannot eliminate the risk of a material recall in the future. Recalls can result in lost sales of the recalled products themselves, and can result in further lost sales while replacement products are manufactured, especially if the replacements must be redesigned or approved by regulatory authorities prior to distribution. If recalled products have already been implanted, we may bear some or all of the cost of corrective surgery. Recalls may also damage our professional reputation and the reputation of our products. The inconvenience caused by recalls and related interruptions in supply, the underlying causal issues, and the damage to our reputation, could cause professionals to discontinue using our products.

Companies are required to maintain certain records of actions, even if they determine such actions are not reportable to the FDA or other regulatory bodies. If we determine that certain actions do not require notification of the FDA or others, the FDA or other regulatory bodies may disagree with our determinations and require us to report those actions as recalls. In addition, the FDA or other regulatory bodies could take enforcement action for failing to report the recalls when they were conducted or failing to timely report or initiate a reportable product action. Moreover, depending on the corrective action we take to redress a product’s deficiencies or defects, the FDA or other regulatory bodies may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner.

Changes in FDA or international regulations related to product approval, including those that apply retroactively, could make us less competitive and harm our business.

FDA and foreign regulations depend heavily on administrative interpretation, and we cannot assure investors that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. Additionally, any changes, whether in interpretation or substance, in existing regulations or policies, or any future adoption of new regulations or policies by relevant regulatory bodies, could rescind, prevent or delay approval of our products, which could materially impact our competitive position, business, and financial results. Further, we or our distributors have obtained regulatory approvals outside the United States for many of our products. We or our distributors may be unable to maintain regulatory qualifications, clearances or approvals in these countries or obtain qualifications, clearances, or approvals in other countries. If we are not successful in doing so, our business and financial condition will be harmed.

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions, agency enforcement actions and harm to our results.

Under the FDA regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In addition, all manufacturers placing medical devices in international markets, such as European Union and Asian markets, are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. In the future, we may experience events that would require reporting to the FDA pursuant to the Medical Device Reporting ("MDR") regulations or to other regulatory bodies pursuant to international regulations. Any adverse event involving our products could result in future voluntary corrective actions, such as product actions or customer notifications, or agency actions, such as inspection, mandatory recall, or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

The decision to file an MDR involves a judgment by us as the manufacturer. We have made decisions that certain types of events are not reportable under the MDR and similar regulations; however, there can be no assurance that the FDA or other regulatory bodies will agree with our decisions. If we fail to report MDRs to the FDA or other regulatory bodies within the required timeframes, or at all, or if the FDA or others disagree with any of our determinations regarding the reportability of certain events, the FDA or other regulatory bodies could take enforcement actions against us, which could have an adverse impact on our reputation and financial results.

If we modify our products we may have to obtain new marketing clearances or approvals, or may have to ease marketing or recall the modified products until clearances or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, including any significant change in design or manufacture, or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared and PMA approved products, and have determined based on our review of the applicable FDA guidance that in certain instances new 510(k) clearances or premarket approvals are not required. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing and/or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Regulatory agencies in other countries similarly require approval or clearance prior to our marketing or selling products in those countries. We rely on our distributors to obtain regulatory clearances or approvals of our products in certain countries outside of the United States. If we or our distributors are unable to obtain additional clearances or approvals needed to market existing or new products in the United States or elsewhere or obtain these clearances or approvals in a timely fashion or at all, or if our existing clearances or approvals are revoked or restricted, our revenues and profitability may decline.

Investigations and allegations, whether or not they lead to enforcement action or litigation, can materially harm our business and our reputation.

Our failure to comply with the requirements of the FDA or other regulators can result in civil and criminal fines, the recall of products, the total or partial suspension of manufacturing or distribution, seizure of products, injunctions, lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any threatened or actual government enforcement action can also generate adverse publicity and require us to divert substantial resources from more productive uses in our business. Enforcement actions could affect our ability to distribute our products commercially and could materially harm our business.

In addition, negative publicity about investigations or allegations of misconduct, even without a finding of misconduct, could harm our reputation with professionals and the market for our common stock. Responding to investigations or conducting internal investigations can be costly, time-consuming, and disruptive to our business.

Risks Related to Ownership of Our Common Stock

The market price of our common stock is likely to be volatile.

The market price for our common stock has fluctuated widely. The closing price of our common stock has varied between a high of $39.90 per share on August 6, 2018 and a low of $10.40 per share on August 7, 2017 during the twelve-month period ended August 6, 2018. Our stock price could continue to experience significant fluctuations in response to factors such as market perceptions, quarterly variations in operating results, operating results that vary from the expectations of securities analysts and investors, changes in financial estimates, changes in the business and market valuations of competitors, announcements by us or our competitors of a material nature, additions or departures of key personnel, future sales of our common stock and stock volume fluctuations. Also, general political and economic conditions such as a recession or interest rate fluctuations may adversely affect the market price of our common stock.

Because we do not intend to pay dividends, stockholders will benefit from an investment in our common stock only if it appreciates in value.

We have not paid any cash dividends on our common stock since our inception. We currently expect to retain any earnings for use to further develop our business, and do not expect to declare cash dividends on our common stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon our earnings, financial condition, capital needs, and other factors deemed relevant by our Board of Directors, and may be restricted by future agreements with lenders. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders purchase their shares.

Our Certificate of Incorporation and Bylaws, anti-takeover provisions of Delaware law, and contractual provisions could delay or prevent an acquisition or sale of our company.

Our Certificate of Incorporation empowers our Board of Directors to issue one or more series of preferred stock, and to determine the rights of each such series as provided in our Certificate of Incorporation. These provisions give our Board of Directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for our common stock. Our Certificate of Incorporation and Bylaws contain other provisions that could have an anti-takeover effect, including the following:

- stockholders cannot act by written consent;
- stockholders cannot fill vacancies on our Board of Directors;
- certain provisions, including those related to changing the number of directors, limiting our stockholders' ability to fill vacancies on our Board of Directors, prohibiting stockholder action by written consent, and amending such provisions, cannot be altered, amended or repealed, and provisions inconsistent therewith cannot be adopted, without the affirmative vote of holders of at least two-thirds in voting power of our outstanding shares of common stock entitled to vote thereon; and
- stockholders must give advance notice to nominate directors or propose other business.

In addition, we are generally subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging tender offers for our common stock or prevent changes in our management.

Ownership of our common stock is concentrated among a few investors, which may affect the ability of a third party to acquire control of us. Substantial sales by such investors could cause our common stock price to decline.

Our largest three investors beneficially own close to 50% of our outstanding common stock. Our investors recommended three of our current five directors. The sale of a substantial number of shares of our common stock by any or all of our largest investors or our other stockholders within a short period of time could cause our common stock price to decline, make it more difficult for us to raise funds through future offerings of our common stock or acquire other businesses using our common stock as consideration.

In addition, having such a concentration of ownership may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding common stock or control of our Board of Directors, including through a proxy solicitation.

Future sales of our common stock could reduce our stock price.

We could issue additional shares of common or preferred stock to raise additional capital or for other corporate purposes without stockholder approval. In addition, we could designate and sell a class of preferred stock with preferential rights over our common stock with respect to dividends or other distributions. Also, we have filed a universal shelf registration statement with the Securities and Exchange Commission. Following the offering reported in this Current Report on Form 8-K, the shelf registration statement is available to cover the future public offering and sale of up to $122,005,850, in equity or debt securities or any combination of such securities. Sales of our common or preferred stock under the shelf registration or in other transactions could dilute the interest of existing stockholders and reduce the market price of our common stock. Even in the absence of such sales, the perception among investors that additional sales of equity securities may take place could reduce the market price of our common stock.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
1.01	Underwriting Agreement
5.1	Opinion regarding legality of securities
23.1	Consent of Samuel Gesten, Esq. (included in Exhibit 5.1).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STAAR Surgical Company

August 9, 2018 By: /s/ Caren Mason
Name: Caren Mason
Title: President and Chief Executive Officer