

MedTech STRATEGIST

**J&J Bounces Back:
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Heating Up?**

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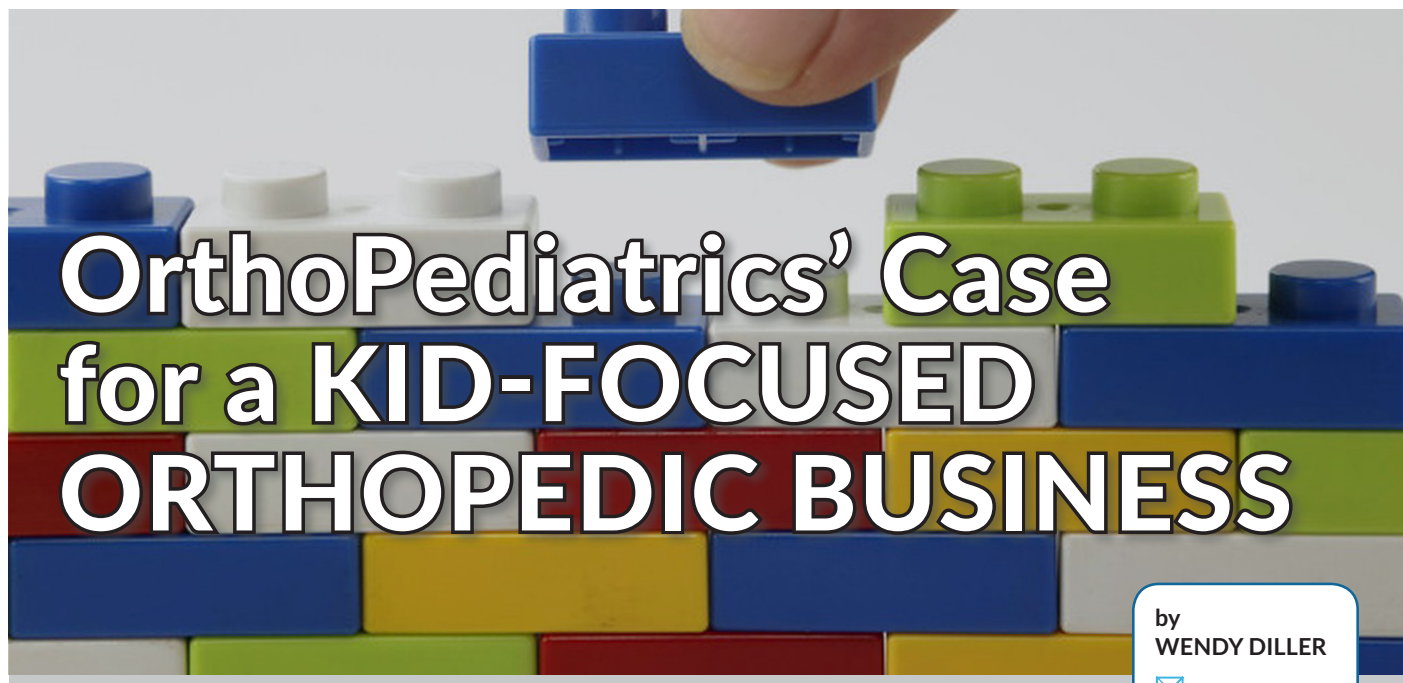
START-UPS TO WATCH

**Nanowear:
Cloth-Based
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Expands Remote
Monitoring's Reach**

Mary Stuart

**SurgiMab: Using
Antibodies to Improve
Oncology Surgery**

Deborah Erickson



by
WENDY DILLER



KEY POINTS

- OrthoPediatrics is building a leadership position in a niche overlooked by most of the orthopedic industry, pediatrics, which is defined by FDA as skeletally immature patients, generally under the age of 21.
- Surgeons and distributors—two key constituents—appear to be enthusiastic about the company's prospects as it makes inroads in some core subsectors of pediatrics, such as scoliosis and trauma and deformity.
- Squadron Capital's sustained support has enabled the company to be methodical and careful over the long-term and most recently to embark on what is by far its biggest venture to date: the \$60 million acquisition of Vilex, a family-owned maker of foot and ankle deformity products.
- While payor pushback and competition are typical challenges in orthopedics, the biggest hurdles for OrthoPediatrics have been gaining credibility and managing continual investment in a broad line of low-volume products.

Backed by a deep-pocketed family fund, 12-year-old OrthoPediatrics is successfully building a brand in the largely overlooked niche of pediatric orthopedics. The company's recent acquisition of Vilex shows its growing confidence, and also underscores the necessity of a "stick-to-the-knitting" strategy in a field that many believe has limited potential.

Peter Armstrong, MD, had a long career in academic medicine as a pediatric orthopedic surgeon before becoming the chief of staff at Shriners Hospitals for Children, with responsibility for overseeing clinical care nationwide in 2007, when several executives from **OrthoPediatrics Corp.** unexpectedly called on him at his offices in Tampa, FL.

The company was about a year old, with no commercial products. Armstrong, who did not know what to make of his visitors, said "Ortho who?" to his administrative assistant. But the strangers had an intriguing proposition that centered on improving the lives of children with orthopedic conditions by supplying technologies and services to help the surgeons who treat them. It was an underserved sub-sector of the market—and Armstrong agreed to join its advisory board.

Armstrong rapidly got more involved, becoming chair of the advisory board before retiring from Shriners in 2012. A few months later,

in early 2013, he joined OrthoPediatics full time as chief medical officer—a move into industry that was new for him. “As I got to know the people and the company, I found they had integrity and the same passion for helping children that I did,” he says.

The apple-pie image is one the company has worked hard to cultivate since it was founded in 2007 by a group of former executives of large orthopedics companies, and one that seems to resonate well in the orthopedics world. The company has been led since 2011 by President and CEO Mark Throdahl, a former group president at Zimmer, who has adamantly maintained OrthoPediatics’ laser-focus on kids.

Under his leadership, the company has built a sustainable, respected brand, emerging as the only pediatric-focused, broad-based supplier of implant systems to childrens’ hospitals and academic medical centers. It has brought together a loyal network of pediatric orthopedic surgeons and motivated, exclusive distributorships. The latter are responsible for generating sales of OrthoPediatics’ line of more than 30 systems, each designed specifically for use in children.

A typical pediatric orthopedic surgeon has in his or her repertoire a medley of procedures: idiopathic scoliosis, ruptured ACL tendon repairs, leg deformity correction in children with cerebral palsy; hip osteotomies to correct angular deformities of the leg. Before OrthoPediatics, surgeons relied largely on adult-sized implants and instrumentation, which they cut down in the operating room to conform to children’s anatomies. The problem has been that “children are not just small adults,” and those approaches at minimum complicated treatment and at worst could disrupt normal growth trajectories, Throdahl says.

The field is ripe for growth, characterized by less reimbursement pressure and greater freedom for surgeon preferences than other areas of orthopedics, and indeed other areas of medicine. With sales of \$70 million in 2018, OrthoPediatics executives believe it is only beginning to tap the surface of an addressable US market of as much as \$1.4 billion (\$3.2 billion worldwide).

The numbers reflect its cautious step-by-step approach—and also the limitations of its potential opportunity. In its early years, OrthoPediatics was capital constrained. All of its new products sailed through the FDA’s 510 (K) regulatory pathway, meaning it wasn’t betting the farm or trying to make a big splash by gambling on one or two hugely disruptive innovations. Further, its reliance on external distributors has given it flexibility and helped it maintain an entrepreneurial culture, without adding a fixed headcount to its balance sheet.

More recently, with an infusion of funds from Squadron Capital LLC and a \$58.6 million 2017 IPO, the cash flow spigot has modestly opened, enabling new initiatives in marketing,

R&D, and physician education. In June, it embarked on its biggest venture to date: the \$60 million purchase of Vilex LLC, a family owned maker of foot and ankle systems for adults and children, and Vilex’s affiliate Orthex LLC. That deal, in addition to adding several important products to the armamentarium, was a further sign of the company’s staying power. Vilex is a big bite for OrthoPediatics, but clearly one that it and the pediatric field are excited about.

That’s no small feat, given the nature of its business, which relies on niche products sold into an emerging medical discipline that is small potatoes compared to multibillion-dollar bread and butter areas like total joint replacement and low back pain. Companies such as **Nuvasive Inc.**, **Stryker Corp./K2M**, **Globus Medical** and **Johnson & Johnson DePuy** may know better—they tend to cherry-pick select opportunities in areas like scoliosis and deformity, but none of these has a dedicated pediatric franchise or distribution channel that specifically woos children’s hospitals, which form OrthoPediatics’ core customer base. Indeed, the biggest risk to OrthoPediatics’ business proposition has been that a company focused solely on children would fail because it would not have enough of a market. Many surgeons were initially skeptical of OrthoPediatics’ long-term commitment, and it has taken considerable time to build credibility among them. “There are easier ways to make a living in orthopedics,” admits Throdahl, who believes that “If OrthoPediatics went away, no one would step into the void” (see *Figure 1*).

The Emerging Pediatric Need: Children are Not Small Adults

A critical factor in designing orthopedic implants for children is the presence of growth plates (physes) at both ends of long bones, in the spinal vertebrae and other bones. These consist of a special type of cartilage through which the growth in length takes place. Damage to these growth plates due to surgery or poor placement of implants can cause growth disturbances in the bone. They are “open” in kids and closed in skeletally mature people—the exact age when this happens varies, although the average age for girls is around 12-14 years old and 14 to 16 years in boys. The other major anatomical differentiator in children is the curvature and smaller size of their bones, although these straighten as the skeleton matures. Therefore, surgeons relying on adult plates and instruments for treating kids reconfigure those devices or run the risk of damaging the physis and curtailing normal growth. This effort often boils down to extra work in the OR—cutting and bending adult-sized plates on the spot to conform to the greater curvature of childrens’ bones. Instrumentation is also inadequate for proper placement of these adult implants in smaller patients.

Furthermore, adult devices simply do not address certain childhood conditions such as cerebral palsy, which may require many surgeries over the years due to a unique set of bone- and tissue-related clinical challenges. Cerebral palsy patients account for approximately a third of the case load for many pediatric orthopedists.

“We’ve been on the market for 10 years with the broadest line of pediatric orthopedic surgical systems, and we are discovering more and more unmet needs,” says Throdahl. A better understanding of biological factors may be more relevant for treating kids, he notes. To take one procedure, surgeons treating adult hip or femoral shaft fractures commonly insert a rigid femoral nail to hold the leg together until it heals. Hip fractures are much rarer in children than in adults, but nails are often used to manage fractures of the femoral shaft, in correcting some cases of intoeing or outtoeing and occasionally in limb lengthening cases. Using rigid nails, improperly inserted in the femur, can, in some cases, cause avascular necrosis (death of portions of the ball shaped head of the femur, or epiphysis), which occurs when the vasculature that is at the top of a pediatric femoral neck that feeds the epiphysis is damaged. To reduce the likelihood of this complication, surgeons who work in the pediatric space typically use a more lateral approach or entry point for the nail through the tip of the trochanter. That requires use of a specially designed curved nail, which OrthoPediatics makes, that avoids the vasculature at the top of the femoral neck.

In another example, treatment for anterior cruciate ligament (ACL) tears remains controversial, even as the incidence grows of these accidents in younger patients. That’s because the current standard of care, surgery, involves replacing the damaged ligament with a graft. In some procedures the surgeon must drill through the growth plates at the lower end of the femur and upper end of the tibia. This has the potential to cause growth disturbances in the tibia, femur or both. OrthoPediatics offers an option that connects the “new” ligament to the bone in a manner that avoids crossing the physes in the lower femur and upper tibia. Because it eliminates the risk of violating each physis, it can be used in much younger children than would otherwise be treated using adult techniques.

In scoliosis cases, likewise, the standard treatment for adolescents has been spinal fusion, but that results in limited mobility and potential for other complications, so interest is growing in alternatives like growth modulation that aim to gradually reduce curvatures as children grow.

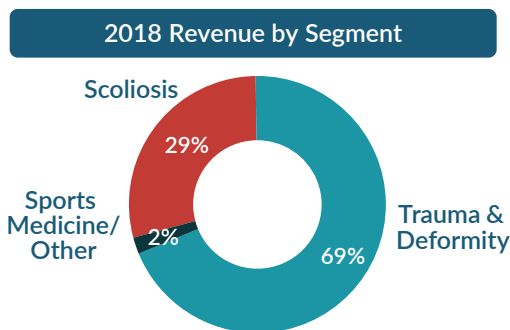
These were the kinds of issues that the company’s founders, led by Nick Deeter, who had worked at Zimmer and other large orthopedics companies, sought to address. Deeter stepped down as CEO in January 2011, when the board brought in Throdahl; he remained chairman but resigned in 2014 and now heads a rival start-up, **WishBone Medical Inc.**, which is involved in patent litigation with OrthoPediatics. Throdahl vehemently insisted on maintaining the company’s *raison d’être*, its mission-oriented, child-centric strategy, instilling discipline over what he thought had become a “chaotic” and overly diversified portfolio. This included a painful restructuring—eliminating 30% of the workforce and adherence to a focus on surgical implants, and movement away from non-surgical aspects of pediatric orthopedic care. “It was a traumatic beginning, unfortunately, but focus pays off and ultimately created a lot of momentum,” Throdahl says.

The Health of the Specialty

The company’s core constituents are the 900 or so pediatric orthopedic surgeons who practice at the nation’s 300 children’s hospitals. They

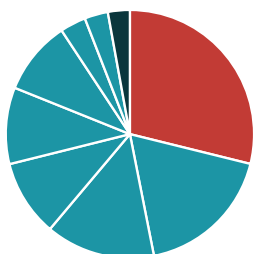
Figure 1

Product Line Diversification

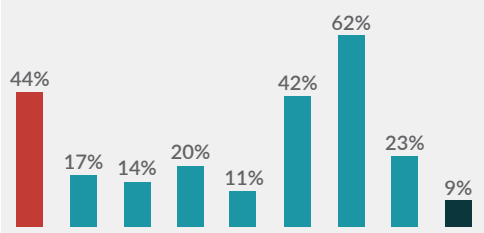


- \$57.6 million sales in 2018, increasing 26%
- Well diversified sources of growth
- All major product families supported FY 2018
- 26% revenue growth
- Firefly, PNP|Femur, and PediFrag were key growth drivers
- All products have comparable gross margins

2018 Revenue by Product Family



2018 Revenue Growth % by Product Family



Source: OrthoPediatics

constitute a comparatively small and modestly expanding clan of subspecialists, which is distinguished by its training—typically a yearlong fellowship—and also by the breadth of conditions it treats—meaning that OrthoPediatics has to be a jack of all trades in a rarified world that doesn't have the luxury of pinning its hopes primarily on high-volume kinds of opportunities.

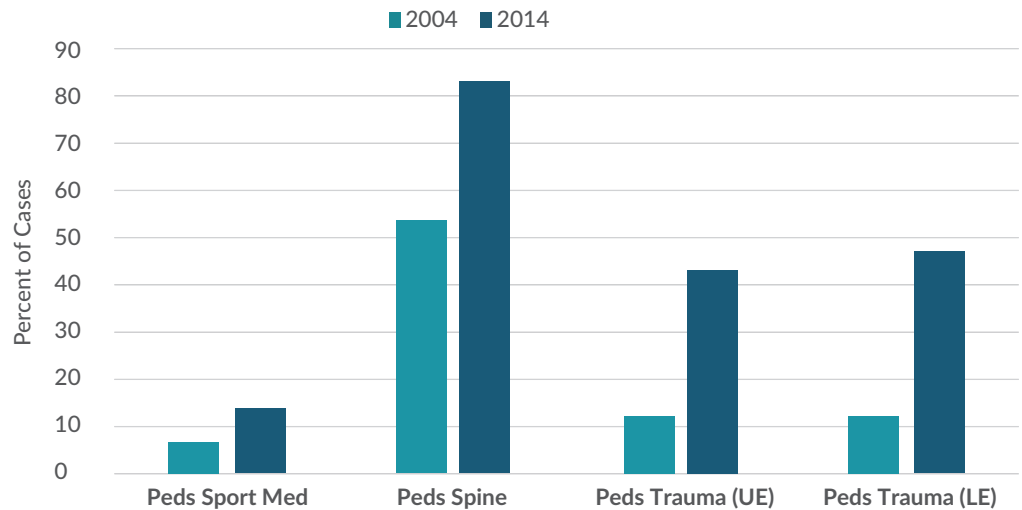
The viability of this specialized workforce greatly impacts OrthoPediatics' prospects and its efforts to form close relationships within it have taken years to develop. Thanks to the IPO, the company now spends considerable time and funds on educating pediatric surgeons and sponsoring their professional meetings. The goal is to advance the entire field, not just sell OrthoPediatics' products, says Throdahl. In a business that is built on a delicate ecosystem, that's an ambitious undertaking. (See *Sidebar: "Culture as a Key Strategy."*)

In a study of the pediatric orthopedic workforce, which appeared in the journal *Orthopedic Clinics of North America* earlier this year, a team of researchers from Washington University in St. Louis looked at fellowship slots and practice volumes to determine if the profession can support the growth in training programs. In a good sign, most of the specialists reported satisfaction with their case-load—but the nature of the questions indicates the field's underlying vulnerabilities.

From 2010 to 2017, the number of fellowship programs for pediatric orthopedic surgeons grew 31% to 47, and the number of available positions grew 27% to 75. From 2004 to 2014, total

pediatric cases performed jumped from 102 to 424. Of these, there was a 65% decline in procedures performed by adult surgeons and 168% increase in those done by pediatric specialists. The biggest shift was the movement of

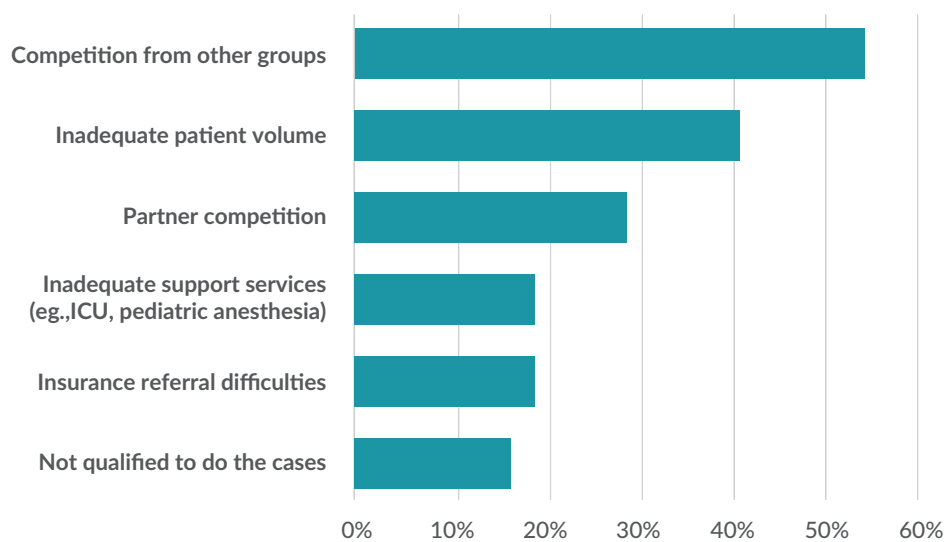
Figure 2
Pediatric Cases Operated by Pediatric Orthopedic Surgeons



Notes: Pediatric cases categorized by type of injury using ABOS database, from 2004 to 2014. LE, lower extremity; Peds, pediatrics; UE, upper extremity. (Data from Hosseinzadeh P, Obey MR, Nielsen E, et al. Orthopaedic Care for Children: Who Provides It? How Has It Changed Over the Past Decade? Analysis of the Database of the American Board of Orthopaedic Surgery. *J Pediatr Orthop* 2019;39(3):e227–e231.)

Source: *Orthop Clin N Am* 50 (2019) 315–325. Reprinted with permission.

Figure 3
Perceived Barriers to Pediatric Volume



Notes: Demonstration of perceived barriers by pediatric orthopedic surgeons not satisfied with their volume of pediatric cases. ICU, intensive care unit. (Adapted from Glotzbecker MP, Shore BJ, Fletcher ND, et al. Early career experience of pediatric orthopaedic fellows: what to expect and need for their services. *J Pediatr Orthop* 2016;36(4):429–432; with permission.)

Source: *Orthop Clin N Am* 50 (2019) 315–325. Reprinted with permission.

adolescent cases from adult generalists to pediatric surgeons. The study further broke down these changes by specific procedure type: half of pediatric extremity cases are still done by adults, but now 83% of all pediatric spine cases are done by pediatric surgeons (see *Figures 2 and 3.*) These numbers are trending in the right direction, but they come off a small base and the wiggle room is tight. The field

OrthoPediatics has to be a jack of all trades in a rarified world that doesn't have the luxury of pinning its hopes primarily on high-volume kinds of opportunities.

is now at “the right number, based on multiple surveys by the Pediatric Orthopedic Society of North America (POSNA), notes Jonathan Schoenecker, MD, PhD, an associate professor of orthopedic surgery and the Endowed Jeffrey W. Mast Chair in Orthopedics, Trauma, and Hip Surgery at Vanderbilt University Medical Center. He adds that the additional fellowships frequently are filled by foreigners. “There is opportunity, but it is limited.”

Encouraging Entrepreneurial Distributors

As important as the physician relationships are in building OrthoPediatics' competitive edge, so too is its distributor network. OrthoPediatics' market share is growing consistently, even in areas where overall sales are flat, because it offers differentiated systems with unique features, says Throdahl. The constant presence in the hospitals of high-quality sales reps is also crucial.

To reach providers, the company relies on a growing network of independent distributors, who employ about 158 sales reps as of November 2019, all of whom work exclusively for OrthoPediatics. In a competitive field, the missionary nature and opportunity to profit in a greenfield setting are big attractions for talent, says Throdahl. Many reps have “taken it on the chin” because of all the ongoing restructuring in the industry and subsequent reduction in sales commissions, particularly by large companies, he observes; OrthoPediatics' sales commissions, in contrast, are “very generous,” he says, and the company isn't in danger of a restructuring, so the arrangement encourages entrepreneurship.

The relationship involves a “shared interest in my business and OrthoPediatics that goes back and forth” and is rare in

the industry, says Tim Hinspeter, president of Trauma-Recon, OrthoPediatics' largest distributor. Hinspeter was a sales rep for a Zimmer distributor in the Hudson Valley looking for more fulfilling work and a chance to own a business when he decided to strike out independently a decade ago. The bet is paying off: his firm employs 16 reps who manage all territory east of Wilmington, Delaware, with a customer base of 40 to 50 hospitals, including some of the busiest pediatric centers in the country. Those numbers should grow, as the plan is to double the size of the business in the next two years, he says.

This dedication has worked in scoliosis, where OrthoPediatics' market share is growing in the double digits—up 40% in 2018 alone—even though the overall market is flat in the US, and competition, including from big spine companies, is fierce. Scoliosis generates only 25% of the company's sales, but its reps are constantly in children's hospitals because of its presence in trauma and deformity, which is a much bigger opportunity. In contrast, the large companies that sell scoliosis devices rarely call on pediatric hospitals and lack the same established relationships with these hospitals to the degree that our people have,” says Throdahl, adding, “It's a matter of supreme indifference to a pediatric orthopedic surgeon that Medtronic's forte is adult surgery and that it sells cervical stuff and artificial discs for adult cases.” Nuvasive is an exception, given it is focused on pediatric scoliosis, but it lacks the breadth of product line that OrthoPediatics offers, he adds. (See “*NuVasive's Intriguing \$380 Million Deal for Ellipse*,” MedTech Strategist, March 16, 2016.)

Swallowing Vilex in Trauma and Deformity

In a sign of confidence, the company last June embarked on its biggest commitment to date: the acquisition of Vilex, a family owned manufacturer of foot and ankle systems for kids and adults, and its sister company, Orthex LLC. In announcing the deal, Throdahl told analysts that Orthex is one of the most promising assets in the pediatric landscape, allowing “us to add six new surgical systems to our sales bag, offer a state-of-the-art external fixation system with a revolutionary software, and enter a new, \$200-million market opportunity.” The deal also blocks the possible entry of a large competitor into pediatric surgery, he added.

The deal was expensive in the eyes of some investors but judging by the company's record third-quarter revenues of \$20.7 million, up 31% year on year, it was the right decision. All-in-all, it closes the biggest gap in OrthoPediatics' largest franchise, trauma and deformity, which comprises 75% of its revenues. Vilex's proprietary *Orthrex Hexapod* circular external fixation system treats traumatic injuries, congenital deformities, and limb lengthening discrepancies using a design that allows the rings to reach up to a

90-degree angle. The system uses hydroxy-apatite coated pins to minimize infection and its strut design allows for easier calibration.

Vilex also comes with a line of foot and ankle systems, which addresses eight of the 12 primary foot and ankle surgeries in children, and a surgical staple system that complements the company's popular *PediPlate* system. Overall, the addition of Vilex/Orthex increases OrthoPediatrics addressable opportunity from 60% to 80% of the pediatric trauma and deformity market and gives it something to offer deformity surgeons who treat children and are unaffiliated with a pediatric hospital, Throdahl told analysts. Vilex had total sales of roughly \$12 million in 2018. Although OrthoPediatrics has not disclosed what percentage of those sales were for

children's procedures, the Orthex hexapod external fixation device, one of the key drivers of the deal, is used almost exclusively on children and generated \$3.1 million in annual revenues. It was Vilex' fastest-growing product, even without the support of a dedicated pediatric distribution channel, which it will obtain under its new owner. A line of foot and ankle systems, the majority of which are used in adult procedures, will be sold off or licensed out—at a value the company is confident it can extract, he says.

The true differentiator of Orthex's hexapod system is the CORA-based x-ray planning software, a point-and-click software that simplifies surgical planning. The software was developed by Abraham Lavi, PhD, founder of Vilex, who worked with one of the world's leading experts on limb

Culture as a Key Strategy

As Chief Medical Officer of OrthoPediatrics, Peter Armstrong, MD, has played a key role in shaping the company's culture and relationships with physicians. The company's founders had come from big orthopedics companies, and, as chairman of the company's surgeon advisory board, Armstrong early on warned them that "Pediatric orthopedists are a completely different breed of surgeon and if you don't recognize their mindset, the company won't work. Their mentality is entirely focused on the child, and they want to know how the company can help them help that child."

Armstrong's role was initially hard to define precisely because no other orthopedics company had a surgeon as chief medical officer (CMO) and models for bringing him in-house did not exist, says CEO Mark Throdahl, adding "we knew we needed someone at a senior level to be voice of the customer and that person could not have a commercial role or he or she would lose credibility with colleagues." The role has evolved over the years, initially from responsibility for clinical education programs, which barely existed when Armstrong joined the company, to more comprehensive training for both surgeons and sales reps.

Armstrong describes himself as "an immigrant" who has had to "learn a new country" and in turn has imprinted an outsider's perspective on that land. This has meant a substantive investment by the company's in the training of both surgeons and sales reps—both Armstrong's purview—along with a firm separation of professional education activities from commercial aims regardless of financial pressures.

Over the years, OrthoPediatrics has become a primary sponsor of the Pediatric Orthopedic Society of North America (POSNA), the main professional association for the field, the biggest sponsor of the European Pediatric Orthopedic Society, and the founding sponsor of several smaller professional societies, including the American Academy of Cerebral Palsy and Developmental Medicine, and PRISM (Pediatric Research in Sports Medicine). The company also runs a social networking site called **Doc Matters**, which doctors can use to exchange information informally on a confidential basis; about half the world's pediatric orthopedic surgeons are members.

The list of top surgeons OrthoPediatrics has reached out to for product collaborations is extensive, and

includes, but is not limited to, Pablo Castaneda, MD, a pediatric orthopedic surgeon at NYU Langone Medical Center, Jonathan Schoenecker, MD, PhD, an associate professor of orthopedics at Vanderbilt University Medical Center, and Min Kocher, MD, PhD, of Boston Children's Hospital, who collaborated on a physis-sparing ACL device. Early on, the company obtained exclusive rights for pediatric applications to the Hamann-Todd Osteological Collection, a well-known collection of human skeletons that belongs to the Cleveland Museum of Natural History. This has served as the basis of several designs, including the first pediatric specific wrist fusion system for children with cerebral palsy and the second generation intermedullary nail for the femur called the *Pediatric Nailing Platform (PNP) Femur*.

"Pediatrics for a time was adapting adult equipment in the OR, but a lot of that changed when OrthoPediatrics came around," Scott Hoffinger, MD, a pediatric orthopedic surgeon at Stanford University, said on a recent KOL call with BTIG medtech analyst Ryan Zimmerman. "It was so welcome, and they have done a really good job. Their devices allow us to be more anatomically specific and precise in what we do."

Figure 4
New Systems & Products Launches, 2017-2018

Trauma & Deformity




Titanium PediPlates System
(Expands physel tethering offering)



Clavicle Plate System
(First pediatric specific system)



Wrist Fusion Plate System
(First pediatric specific system)




PediFlex Advanced



Pediatric Nailing Platform | FEMUR
(Expands into adolescent cases)

Scoliosis



FIREFLY Pedicle Screw Navigation Guides
(Complementary to RESPONSE Spine System)




FireFly S2/Alar



RESPONSE 4.5/4.75/5.0mm System
(Maximizes intraoperative flexibility)

Sports Medicine



Medial Patella Femoral Ligament Reconstruction System
(Complementary to ACL Reconstruction System)

Source: OrthoPediatics

Figure 5
New Systems & Product Launches, 2019 and Beyond

Trauma & Deformity

Launched Sept '19




Next Generation Cannulated Screw Systems

Launching 4Q19




QuickPack Bone Void Filler

Launched Nov '19



PediFoot (First pediatric system)

Launching 4Q19/1Q20




Slipped Capital Femoral Epiphysis System

Development In Process



Osteogenesis Imperfecta Nail System


Development In Process



PNP | Tibia

Scoliosis

Launched Feb '19



BandLoc DUO System

Development In Process



Neuromuscular Scoliosis System

Source: OrthoPediatics

deformity, Dror Paley, MD, a pediatric orthopedic surgeon who is founder of The Paley Institute of West Palm Beach. Paley was responsible for introducing one of the mainstays of limb deformity correction, the ILLizarov method of external fixation into the US in 1986 and has conducted more than 17,000 limb lengthening and reconstruction surgery procedures. The software they developed is designed specifically for the external fixation device, but may have broader uses, and the three young software engineers who created it are now part of OrthoPediatics team.

A Key to Success: A Loyal Investor

In addition to maneuvering to sell the adult business, the Vilex deal required external financing. In stepped Squadron Capital, the company's long-term backer and an investment arm of the Pritzker hotelier family. Its deep pockets and patience have enabled the company to re-invest in a field that is taking time to emerge as a substantial commercial opportunity.

Over the years, Squadron had given or lent OrthoPediatics a total of \$80 million, in exchange for a majority stake in the company and the right to four seats on the board of directors. And even though that equity position has declined following the IPO and now stands at 37%, Squadron put up additional money as a loan for the Vilex deal.

Meanwhile, the company has used proceeds from the \$58.6 million IPO to advance to the next level. A key priority has been to expand its deployment of consignment sets into the field. This is a strategy that large companies undertake to make sure their kits and instruments are always available to surgeons on demand, reducing or eliminating wait times for the arrival of relevant equipment. Prior to the IPO, the company spent \$3.5 million on deploying kits; in the first half of 2019, that number rose to \$12 million, with expectations of reaching \$15 million to \$17 million for the full year. This has prepared the company well for “the strong sales we are now achieving during the summer surge in elective surgeries,” Throdahl told analysts on the company’s second-quarter earnings call in August.

The IPO riches also are enabling accelerated R&D and a series of new product launches. The company has been introducing five- to six new products a year. In 2019 alone, it received FDA 510 (k) clearance for *PediFoot*, the first pediatric-specific system to address common foot deformities, as well as fractures of the small bones in the extremities. It also launched a new slipped capital femoral epiphysis system, new cannulated screw systems, and *Bandloc DUO*, an enhancement to its *Bandloc* line of pedicle-sparing implants for stabilization during spine fusion. That does not include the additional devices from Orthex/Vilex. It now sells 33 systems, up from 26 a year ago (see Figures 4 & 5).

All of these initiatives have directly contributed to its consistent 20%-plus growth rate per year. But just as important, while many surgeons and key constituents were initially skeptical of OrthoPediatics, the IPO gave a boost to the company’s credibility—and it has helped with recruiting by convincing potential hires that the company is worth a leap on their part.

Generating sales from a broad collection of low-volume products is always an expensive and relentless business proposition. Twelve years in, profitability continues to be elusive, and it is debatable whether room for substantial expansion exists in the highly parsed specialty it services. Over time, however, OrthoPediatics has demonstrated staying power and is now intent on broadening its portfolio, bulking up its R&D, including compiling higher-quality clinical data, and continuing to hire and train sales reps. Currently, it spends about 8% of sales on R&D, up from 4% to 6% prior to the IPO, with plans to stay at that rate even as sales grow, says Fred Hite, CFO. With more substantive funding, the company intends to invest in clinical work that tracks outcomes over time and generates data sorely lacking in the field. But question marks remain on how far it can go and how big it can get given the realities of pediatric orthopedic practice.

As it grows, the key will be to stay focused and continue with the steady drumbeat of new products. This means more acquisitions are likely, albeit not likely on scale of Vilex, so much of the work will be done internally or through physician-collaborators. The good news is, large companies still seem reluctant to compete; in fact they have approached OrthoPediatics with offers to sell their

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products, a phenomenon that has been enhanced by the company’s increased credibility since the IPO, says Throdahl. Despite some analysts’ speculation that a large buyer will swoop in, he is quick to disparage an interest in selling the business. “It’s not clear what the motivation would be for that,” he says. Over time, Throdahl, along with Armstrong, Hite, and the rest of management, are excited about the entire field’s growth. “We view this as a vibrant field for attracting new surgeons. As far as we can tell from IMS surgical procedure data, 62% of orthopedic surgeries occur in pediatric academic centers. This is the basis of our addressable market and it is growing,” Throdahl says.

At the same time, the inability to date to balance the books may be less of a concern for the strategic buyers who are most likely to enter OrthoPediatics’ orbit at some point. That would fall in line with the well-trod strategy of innovative medtech entrepreneurs zeroing in on niche markets, building surgeon loyalty and getting bought out by large companies eager to tap those markets. It’s a truism that such companies are most valued for their market leader positions and ability to define brands, even at the expense of profits, says Anthony Viscogliosi, managing director of Viscogliosi Partners, and a serial entrepreneur who sold the orthopedic extremities company Small Bone Innovations to **Stryker Corp.** for up to \$375 million in cash in 2014. “Strategic buyers will pay a premium for niche companies based on their market leadership position, gross margin, and growth rate, and their sustainable innovation. They will make these niche players profitable by integrating them into their own much larger distribution channels,” Viscogliosi says. OrthoPediatics, he believes, “is going in a great direction.” 