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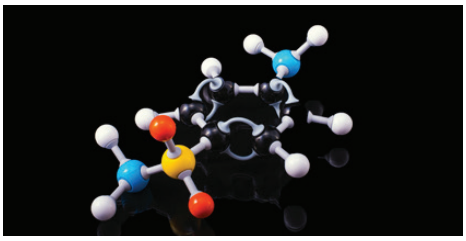
Orthopedics This Week

WEEK IN REVIEW



BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Earnings season is done and investors are rapidly putting 2020 behind them. What's ahead? A post-pandemic market. What might that look like to the Wall Street crowd? Think Roaring Twenties. Broad based purchases of equities. Rising rates of inflation. Overall bullish markets with a decidedly tech and consumer flavor. And, interestingly, investor risk tolerance seems to be ticking up already. Witness micro-cap XTANT which soared 186% last week on the strength of internet based, small investor buying.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	3	Zimmer	12.91%	6.85%	New #1 in OTW's Power Rankings of the best values in Orthopedics. Biggest news, CEO Hansen officially to become Chairman of the Board.
2	1	Pacira	9.65	6.71	Solid report for 2020—$430 million in sales, $145 million in GAAP earnings. With EU approval of Exparel, 2021 is looking outstanding.
3	NR	Orthofix	(3.24)	10.95	Wall Street liked OFIX's 2020 report. Biggest takeaway was how well Serbousek and team navigated the elective surgery cancels.
4	5	ConMed	7.71	7.04	CNMD remains a solid value in orthopedics—2021 will be a transition year. Key focus will be on R&D. Needs more hits than misses.
5	4	Integra LifeSciences	16.78	(0.47)	The word on the Street is that IART "crushed" analysts' earnings estimates for 2020—in a good way. Now comes 2021. Can management repeat?
6	6	Dynatronics	(6.17)	27.97	DYNT's Bird and Cronin sub signs key distribution deal. Good news. But DYNT's sales and earnings have yet to catch up to investor enthusiasm.
7	NR	NuVasive	4.78	4.99	NUVA buys Simplify Medical adding a key cervical disc arthroplasty product to the portfolio. Back on the Power Rankings.
8	2	Johnson & Johnson	26.06	(5.61)	Sell on news. FDA grants emergency use status for JNJ's single-shot COVID vaccine, and investors sell off roughly $20 billion in JNJ equity.
9	9	Surgalign	(3.53)	34.81	Biggest news remains SRGA's $37 million of new equity, acquisition of HOLO Surgical and a new management team.
10	7	Stryker	24.40	5.17	Solid 2020 report, notably over 100 Mako units sold in Q4. But COVID-19 concerns in Q1 and Q2 of 2021 tamp down enthusiasm.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Xtant Medical Hldgs	XTNT	$4.33	$337	186.75%
2	Aurora Spine	ASG.V	$0.68	$34	94.03%
3	Surgalign Holdings	SRGA	$2.44	$260	34.81%
4	AxoGen	AXGN	$22.10	$887	28.64%
5	Dynatronics Corp	DYNT	$1.51	$23	27.97%
6	SeaSpine Hldngs Corp	SPNE	$18.92	$523	16.00%
7	Alphatec Holdings	ATEC	$16.05	$1,259	13.43%
8	Orthofix	OFIX	$46.51	$908	10.95%
9	SINTX Technologies	SINT	$2.05	$51	9.04%
10	MiMedx Group	MDXG	$9.91	$1,100	8.42%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Lattice Biologics	LBL.V	$0.05	$5	-24.73%
2	MicroPort Scientific	853	$5.89	$10,668	-21.34%
3	Smith & Nephew	SNN	$38.85	$17,038	-11.04%
4	Flexion Therapeutics	FLXN	$11.02	$543	-10.91%
5	Johnson & Johnson	JNJ	$158.46	$416,541	-5.61%
6	Nevro Corp	NVRO	$165.18	$5,719	-2.43%
7	Integra LifeSciences	IART	$68.34	$5,766	-0.47%
8	Globus Medical	GMED	$62.50	$6,232	1.81%
9	CryoLife	CRY	$25.25	$984	3.23%
10	Medtronic	MDT	$116.97	$157,614	4.91%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Surgalign Holdings	SRGA	$2.44	$260	4.39
2	Pacira	PCRX	$73.50	$3,193	20.61
3	Johnson & Johnson	JNJ	$158.46	$416,541	23.69
4	Integra LifeSciences	IART	$68.34	$5,766	32.17
5	Stryker	SYK	$242.69	$91,300	37.73

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$46.51	$908	309.04
2	MicroPort Scientific	853	$5.89	$10,668	230.50
3	ConMed	CNMD	$123.06	$3,562	124.76
4	Medtronic	MDT	$116.97	$157,614	52.05
5	Zimmer Biomet	ZBH	$163.06	$33,893	48.69

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Surgalign Holdings	SRGA	$2.44	$260	0.29
2	Pacira	PCRX	$73.50	$3,193	0.49
3	Stryker	SYK	$242.69	$91,300	3.64
4	Globus Medical	GMED	$62.50	$6,232	3.65
5	Integra LifeSciences	IART	$68.34	$5,766	4.27

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$46.51	$908	32.88
2	ConMed	CNMD	$123.06	$3,562	9.04
3	Smith & Nephew	SNN	$38.85	$17,038	8.27
4	Medtronic	MDT	$116.97	$157,614	5.73
5	Johnson & Johnson	JNJ	$158.46	$416,541	4.46

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Dynatronics Corp	DYNT	$1.51	$23	0.42
2	Surgalign Holdings	SRGA	$2.44	$260	0.84
3	Lattice Biologics	LBL.V	$0.05	$5	1.49
4	Orthofix	OFIX	$46.51	$908	2.23
5	Aurora Spine	ASG.V	$0.68	$34	2.32

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	SINTX Technologies	SINT	$2.05	$51	73.44
2	Nevro Corp	NVRO	$165.18	$5,719	15.80
3	OrthoPediatrics Corp.	KIDS	$54.46	$1,065	14.68
4	MicroPort Scientific	853	$5.89	$10,668	13.44
5	Alphatec Holdings	ATEC	$16.05	$1,259	11.10

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Hospitals? Profits Down and, By the Way, Cash Flow Sucks

BY ROBIN YOUNG

Source: Wikimedia Commons, Alberto Guiliani and Pablo Jarrin

How are hospitals doing? Not so well. Profits are down and cash flow sucks—which has a direct impact on orthopedic product sales and pricing.

A new *study* from Kaufmann, Hall & Associates, LLC, management consulting paints a sobering picture of hospital financial health as we pass COVID-19's one year anniversary.

As 2020 was winding down, U.S. hospitals were grappling with a flood of new COVID admits (125,423 COVID-related hospitalizations in December, up 30% from November). Expenses spiked, profitable activities like elective orthopedic procedures were pushed back and U.S. hospitals in the aggregate struggled to break even—and most did not.

Hospital Profitability Hit 0.3% of Revenue in December

Quoting directly from the Kaufmann Hall January 2021 Flash Report:

"COVID-related hospitalizations—which have steadily increased since early September—climbed to a December high of 125,423 nationwide at month's end, up more than 30% since late November, according to The COVID Tracking Project."

As a result, "The median Kaufman Hall hospital Operating Margin Index* for all of 2020 was 0.3%, not including federal CARES funding. Operating [Profit] Margin was down 55.6% (4.9 percentage points) for January through December without CARES. Operating EBITDA Margin fell 34.8% (4.9 percentage points) in 2020 without the federal funding."

CARES, by the way, refers to the Coronavirus Aid, Relief, and Economic Security Act which assists small businesses that have been affected by the COVID pandemic. Even with CARES funding, hospital profits were down by double digit rates.

Aggregate hospital profitability, measured as a percent of revenue, fell from 5.2% of sales to 0.3% of sales in December 2020.

Details

Because of COVID, hospital inpatient volumes rose in 2020. Average patient days in the hospital were up 4.5% over 2019 levels. Conversely, patient discharges were down 4.3% year-over-year. Which, of course, means that average length of stays, a key barometer of costs, rose 11% over 2019 levels.

Emergency rooms bore the biggest brunt of the COVID spike. ER patient volumes dropped 16.2% from 2019 levels. Second most affected hospital department—and this had a direct effect on orthopedic company revenues—was operating rooms. Operating room minutes fell 10.5% in 2020.

Fear of COVID prompted many patients to stay away from hospitals which, in turn, changed the Inpatient/Outpatient dynamic and, therefore, also drove expenses up—way up. The Total Expense per Adjusted Discharge and Labor Expense per Adjusted Discharge popped 14.4% in 2020.

One final stat really stood out as we read the Kaufmann Hall report. In December, again for the overall hospital system in the United States, Drug Expenses per Adjusted Discharge leaped 44% in December versus 2019 December levels. This was almost entirely due to COVID surge around the 2020 holiday season.

Outlook

As we write this article, hospitalizations for COVID are dropping sharply and by the end of March, approximately 175 million doses of 3 different COVID vaccines will be in broad U.S. distribution.

Operating rooms are back to routine use. Patients, particularly those over the age of 65, the prime population for orthopedic and spine care, are returning to their doctors and scheduling long delayed procedures.

And yet. Hospitals have yet to recover financially from 2020 and remain cautious. To quote from the Kaufmann report:

"The next few months are expected to be rough, as the nation's hospitals and health systems cope with rising COVID-19 infections as people congregate indoors over the colder winter months, and as the new, more contagious variant of the virus spreads nationwide."

"The CDC projects the new variant could be the most prevalent COVID-19 strain in the U.S. by March. Hospitals already saw COVID-19 hospitalizations jump 6% between December 31 and January 7, likely due to infections from holiday related gatherings. As of January 7, hospitals reported that 79% of intensive care beds were occupied nationwide, up 2 percentage points from just one week prior."

Finally, in *OTW*'s view, the end of the COVID effect on clinic and hospital revenues and cash flow is within sight. Certainly, we think, by the second half of 2021, the vast majority of the U.S. population will have been vaccinated, which should bring hospital and clinic activity back to pre-COVID levels. Among the permanent changes will be, we think, the percentage of orthopedic care being offered within the ambulatory surgery center (ASC) setting.

For suppliers of orthopedic implants and instruments, we continue to expect that there will likely be a sales rebound effect coming from two factors: the full return of elective surgeries and in-person surgeon and company meetings like American Academy of Orthopaedic Surgeons (AAOS) in late August/early September.

* Note: The Kaufman Hall Hospital Operating Margin and Operating EBITDA Margin Indices are comprised of the national median of our dataset adjusted for allocations to hospitals from corporate, physician, and other entities. ♦

New Biomaterial May Better Control Implant Degradation

BY TRACEY ROMERO

A team of American and British researchers have discovered a way to fine-tune a new biomaterial to control degradation and certain mechanical properties without loss of strength.

In a new study, "Concomitant control of mechanical properties and degradation in resorbable elastomer-like materials using stereochemistry and stoichiometry for soft tissue engineering," published in *Nature Communications*, the researchers show how the addition of varying amounts of succinic acid can be used to control the rate the material degrades within the body without the material losing strength.

A team at the University of Birmingham in the United Kingdom and Duke University in the United States designed the thermoplastic elastomer-like material for use in soft tissue repair. It has many applications including treating torn ligaments and other sports-related injuries.

The researchers found that it degrades gradually over a period of four months until eventually healthy tissue replaces the implant. They tested the material's biocompatibility and safety in rat models.

The team explained that the structural changes needed to increase degradation of a biomaterial would normally weaken the material, but they were able to tweak the materials' mechanical properties so there would be no loss strength.

Source: Unsplash and Terry Vlisidis

This adaptability is a game changer they said.

"Biological tissues are complex with varying elastic properties. Efforts to produce synthetic replacements that have the right physical characteristics and that can also degrade in the body have been ongoing for decades," said study co-author Andrew Dove, Ph.D., professor of sustainable polymer chemistry at the University of Birmingham.

"Part of the challenge is that a 'one-size fits-all' approach doesn't work. Our research opens up the possibility of engineering biological implants with properties that can be fine-tuned for each specific application."

"The materials we have developed offer a real advance in the ongoing search for new biomaterials. The tunable nature of the material makes it suitable for a range of different applications from replacement bone to vascular stents to wearable electronics. Additional work to prove the biocompatibility of the material and its use in more advanced demonstration is ongoing," added Matthew Becker, Ph.D., Hugo L. Blomquist Distinguished Professor of Chemistry at Duke University. ♦

Remembering Orthopedic Surgeon Manmohan Singh

BY TRACEY ROMERO

Orthopedic Surgeon Manmohan Singh, M.D., passed away February 13, 2021 at his home in Olympia Fields, Illinois, after a long illness with Parkinson's disease.

Best known as the originator of the "Singh Index," a method used to predict the risk of hip fracture due to osteoporosis, Singh will always be remembered for both his brilliant mind and for his caring heart. His wife Manjit and their two sons Gurmelt and Kirpal were him in his last moments.

Singh was raised by his grandfather in Patiala, India. Although surrounded by love, he faced a lot of adversity early in life, including a childhood accident that left him with severe burns on his legs which caused an infection that almost killed him.

After medical school, he came to the U.S. on a Fulbright Scholarship in 1969 working with Drs. Mel Post and Leo Weinstein in the orthopedic department at Michael Reese Hospital in Chicago. Then after training at Mayo Clinic in Rochester, Minnesota, Singh became the director of orthopedic research at Michael Reese where he continued to explore better ways to diagnose and treat osteoporosis.

During his career, he also specialized in bone fracture, carpal tunnel syndrome, scoliosis, and sports medicine.

Singh quickly fell in love with the city of Chicago and became an avid White Sox fan. He also loved to take his family out to all of Chicago's best restaurants and to the debut of films that were given "Two Thumbs Up" by Siskel and Ebert. He also enjoyed art and spent many hours at the Art Institute and the Museum of Contemporary Art.

Manmohan Singh, M.D. / Courtesy of Legacy.com

What he will most be remembered, though, for his kindness to his patients and to the residents he trained. For many years, he would host a party at his home for the graduating class.

His favorite film was "The Adventures of Robin Hood" which his family says is what inspired him to be such a generous philanthropist as well. The family asks that in lieu of cards or flowers that gifts be made to one of his favorite charities—Save the Children, PO Box 97132, Washington DC, 20090-7132 or to UNICEF USA, 125 Maiden Lane, New York, NY 10038. ♦

COMPANY

Josh Pang: New Chief Commercial Officer at Orchid Orthopedic

Josh Pang, former vice president of Orthopedic Sales at ConMed, is the new chief commercial officer at Holt, Michigan-based Orchid Orthopedic Solutions. While at ConMed, Pang managed the U.S. sales force for the orthopedic business; he has also worked at Smith & Nephew, Pfizer and J&J.

"One of the key enablers of Orchid's business strategy is a focus on our customers. We know that having a strong relationship with our customers helps drive growth. To continue building on our foundation of customer relationships, I am pleased to announce the addition of Josh Pang to the Orchid Leadership Team," said Nate Folkert, Orchid's CEO.

Prior to Orchid, Pang held roles in original equipment manufacturer (OEM) sales, downstream marketing and people management. Mr. Pang told *OTW*, "One of the things I'm most excited about is understanding our customers. In previous roles, I had the opportunity to learn the root cause of why our customers were doing what they were doing, then help them solve what they were going after. In my new role, I plan to take a similar approach: understand customers' needs and work together to meet their goals as well as Orchid's."

Joshua Pang / Courtesy of Orchid Orthopedic Solutions

Furthermore, said Pang, "My first step is to understand Orchid's capabilities and what we have to offer. I've worked in the medtech industry, but contract manufacturing is new to me. I'm looking forward to working in a different space, and I want to dig deep and understand the business. I also want to get to know the customers who are so loyal to us. What are they trying to accomplish, and how can we be responsive to and anticipate their needs? It's all about taking care of and building relationships with customers, which has been a primary focus throughout my career."

"Joining a company is like joining a new family. There are a lot of talented people here. I want to get to know everyone, and I'm excited to learn and grow with the organization. I really like meeting new people and figuring out how we can get better together." — *EH*

Jay Patel, M.D.–New Chief Strategy Officer at Hoag

Jay J. Patel, M.D., who brings the perspective of a former consultant with a strategic consultancy group, is the new chief strategy officer at Hoag Orthopedic Institute (HOI) in Irvine, California. Dr. Patel replaces James Caillouette, M.D., a founder of HOI, who held the position for more than 10 years. Dr. Patel will oversee long-term planning and strategy for the facility's growth.

"Dr. Patel is unique at HOI in that beyond his superb training as a hip and knee surgeon, he also worked as a consultant for McKinsey—a world renown strategic consultancy group. This combination of expertise will be extremely valuable for the institution moving forward," said Dr. Caillouette, who will remain an active surgeon and leader at HOI.

Jay J. Patel, M.D. / Source: Hoag Orthopedic Institute

An orthopedic surgeon specializing in total joint replacement and adult reconstructive surgery. Dr. Patel is experienced in "…anterior approach hip replacement surgery, computer navigation and robotic joint replacement." Dr. Patel, also "…co-director of the HOI Joint Replacement Fellowship…is published in multiple areas of orthopedic research including, computer navigation systems for total joint replacement, revision of complex hip and knee replacement surgery, and orthopedic clinical outcomes."

After graduating Summa Cum Laude and Phi Beta Kappa from Harvard University with a bachelor's degree in biochemical sciences, Dr. Patel earned his M.D. and a master's degree in mechanical engineering from Stanford University. During this period he "…was a member of the Stanford Biodesign Innovation Program where he researched computer navigation systems for joint replacement surgery and assisted in the design of multiple orthopedic surgical devices."

"Dr. Patel completed his fellowship in adult reconstruction, arthritis, and joint

replacement surgery at the Hospital for Special Surgery in New York City. Dr. Patel did his orthopedic surgical residency at the University of California, Irvine, under the guidance of Dr. Robert Gorab and Dr. Steven Barnett."

"It is an honor to follow in the footsteps of Dr. Caillouette and I will continue in the spirit of his sage leadership," said Dr. Patel. "His vision for the future of HOI is my vision as well, and we plan to build on our successful past as we continue to make the institution the best orthopedic surgical facility in the world."

OTW asked Dr. Patel about how his time at McKinsey will inform his new role Dr. Patel said, "McKinsey provides a great framework to analyze complex business problems objectively. While at McKinsey, I was able to apply these frameworks to a wide array of strategic decisions in different industries for my clients."

"At HOI our primary goal is to provide the highest level of musculoskeletal care to our patients and community. Today's health care and economic environment are changing rapidly. We view it as our responsibility to remain a nimble organization that continues to scale our ability to deliver this level of care. HOI was founded by a team of physicians, leadership, and staff that embraced an entrepreneurial spirit. Now 10 years in, it is our challenge to leverage that same entrepreneurial spirit to our next phase of growth. Whether it is developing ambulatory surgery centers, increasing our physician network, or developing new payment models our underlying challenge is to scale the quality of care we provide today." — *EH*

Looking Good! Alphatec's New Headquarters

Alphatec Holdings, Inc. (ATEC) new headquarters is a beauty to behold. The team at ATEC decided to design their new home from the ground up, starting in early 2018 and finishing up most impressively earlier this year.

For a company focused on "revolutionizing the approach to spine surgery," its "home" needs to embody and reflect those goals. Specifically, the ATEC team designed its new facility to "inspire collaborative innovation, increase productivity, and support the Company's [ATEC's] rapid growth."

ATEC is, of course, a well-known small cap spinal implant manufacturer whose product offerings cover anterior cervical discectomy and fusion, anterior lumbar interbody fusion, lateral interbody fusion, transforaminal lumbar interbody fusion, posterior cervical fusion, posterior fixation, and posterior lumbar interbody fusion.

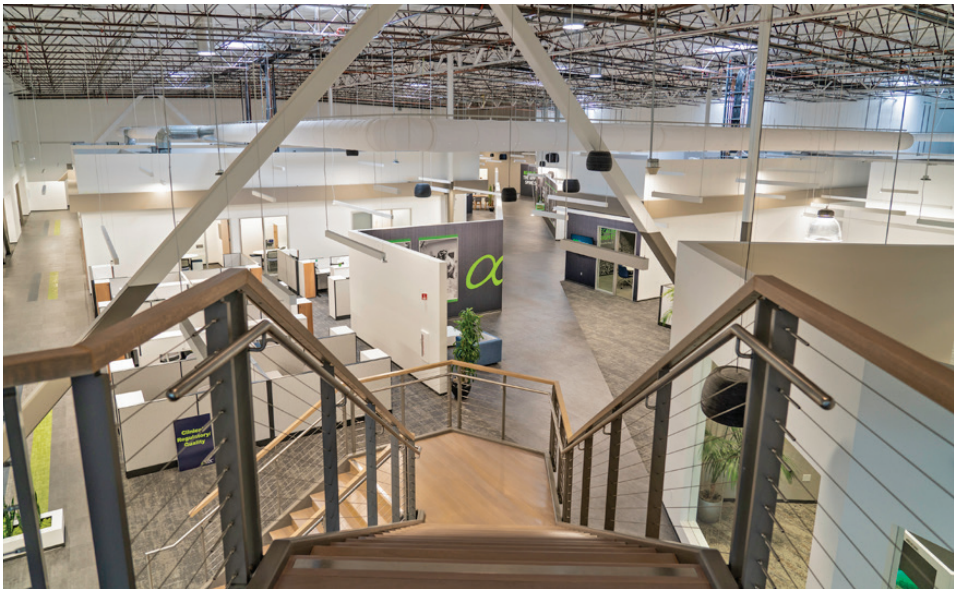
The company has grown rapidly—staff virtually doubled since 2017, to nearly

ATEC New Headquarters front view / Courtesy of Alphatec Holdings, Inc.

ATEC New Headquarters back view / Courtesy of Alphatec Holdings, Inc.

Seven-station cadaveric lab viewable from all lobby locations

Indeed, ATEC's business is in the operating room!



Inside is open and built for collaboratoion and teamwork

300 employees. Furthermore, senior management has made it very clear that growth is just starting. If, as promised, ATEC adds "significant number" of positions over the coming months and years, well, a new headquarters became necessary.

World Class Surgeon Training

What can surgeons and staff expect from the new facility?

The new 120,000 square-foot facility boasts "a world-class cadaveric lab, a state-of-the-art machining center, an extensive biomechanical lab, expanded office space and meeting areas, and well-appointed outdoor spaces to support working, meeting and fitness activities. The seven-station cadaveric lab is viewable through floor-to-ceiling windows from the lobby and will be central to increased engagement of ATEC's new procedures and products."

OTW spoke with ATEC Chairman and Chief Executive Officer Pat Miles about the new headquarters. Miles told us, "The most exciting feature of the new headquarters is the world-class cadaveric lab, which has been designed to reflect a singular message: our business is in the operating room."

"We have more than doubled the number of cadaveric stations in the lab to enable us to better meet increased demands for training and allow for robust collaboration between our product development teams and surgeon partners. The lab boasts seven stations and is viewable through floor-to-ceiling windows from the lobby. It will be central to increased engagement of spine surgeons and sales professionals preparing to employ ATEC's new procedures and products." — *KD*

Vafa Jamali New CEO of…ZimmerBiomet's "StayTuned"

This company needs a name. In the meantime, the face of Zimmer Biomet's "NewCo" is a rising star in med devices, former Medtronic exec, Vafa Jamali.

When will "NewCo" get a name? These days, thinking of a name takes forever, costs hundreds of thousands of dollars, if not millions and the final result is an otherwise nonsense word which offers vague impressions of whatever qualities senior Zimmer Biomet execs were aiming for.

For now, we'll call "NewCo", StayTuned.

StayTuned (aka: NewCo) is an independent, soon to be publicly traded company formed by Zimmer Biomet to house its spine and dental businesses—a nearly $1 billion enterprise. The whole

Vafa Jamali / Source: LinkedIn

spin-off transaction, a very complex maneuver, will likely close by mid-2022. For *OTW*'s initial coverage of the transaction, see "A Look Into Zimmer Biomet's Spine and Dental Spin Off."

Jamali expressed excitement about joining StayTuned, commenting, "I'm so excited to join NewCo at this pivotal time in the company's creation. This is a prime opportunity to leverage my experience in execution and value creation for NewCo."

Jamali has over 25 years of medical device industry experience and has spent more than 20 years serving top companies in executive leadership positions. His impressive resume includes Medtronic, Covidien, Cardinal Health, and Baxter. He currently serves on the board of directors for Canada-based Baylis Medical, a company that develops and commercializes cardiology and spine medical devices.

In his most recent role as Rockley Photonics Inc.'s chief commercial officer, he "led commercial strategic planning for the early-stage integrated optics solutions provider." Prior to joining Rockley Photonics, he served as senior vice president and president of respiratory, gastrointestinal and informatics (RGI)

within Medtronic's minimally invasive therapies group (MITG). In that role, Jamali led 10,000 team members across four businesses and 14 manufacturing sites.

Zimmer Biomet President and CEO Bryan Hanson spoke to Jamali's experience, stating, "Vafa's [Jamali] extensive knowledge and experience in building teams, developing long-term growth strategies, prioritizing resources, driving execution and delivering growth across the medical device industry make him the ideal leader to shape the direction of NewCo and move the business forward."

Hanson continued, "I look forward to partnering with Vafa [Jamali]—and the leadership team that he builds—through this important transition so we can position NewCo for maximum success." —*KD*

Dr. Saif Rathore Joins IncludeHealth's Medical Advisory Board

Columbus, Ohio-based IncludeHealth, Inc. has announced that Saif Rathore, M.D., Ph.D. has joined its Medical Advisory Board.

Dr. Rathore is a medical data analytics executive. During his career, Dr. Rathore has served as head of data and analytics innovation at Cigna-Evernorth, associate partner and medical director of pharmaceutical and medical products group at McKinsey & Company, and faculty at the Yale School of Medicine. Dr. Rathore earned his Ph.D. in Epidemiology and Medical Degrees from Yale University and completed his training in internal medicine at Massachusetts General Hospital. Founded in 2009, IncludeHealth is a digital health and performance

Saif Rathore, M.D., Ph.D. / Courtesy of IncludeHealth, Inc.

Advertisement

company focused on musculoskeletal care. It provides digital tools to support "onsite and remote musculoskeletal services." IncludeHealth's technology is used in various industries including orthopedics, neuroscience, pediatric care, senior care, government, and general wellness.

IncludeHealth's platform enables the "onsite and remote delivery of personalized, measured care." Its products consist of IncludeCloud™, IncludeForm™, and IncludeConnect™. For *OTW*'s coverage of the launch of IncludeConnect, see "New Product Digitizes Rehab on Any Equipment."

Founded in 2018, the IncludeHealth Medical Advisory Board is led by one of its founders, John M. Tew, Jr., M.D. Dr. Tew is a neurosurgeon with the Mayfield Clinic and clinical director of the University of Cincinnati Neuroscience Institute. He has more than 45 years of medical leadership experience.

The IncludeHealth Medical Advisory Board is a specific advisory board to IncludeHealth. The board focuses "on broadening the medical applications and research aspects of IncludeHealth's digital platform." Unlike the board of directors, it does not have controlling rights or the fiduciary responsibilities.

OTW spoke with Dr. Rathore about his decision to join the IncludeHealth Medical Advisory Board. "The technology and overall product that IncludeHealth has created is truly distinctive. In my previous roles, I've had occasion to see and evaluate many virtual care providers and very few have the transformative potential of IncludeHealth."

Dr. Rathore continued, "Ryan [Eder] and his team are building something quite special and am thrilled to be a part of the journey." — *KD*

SITES Medical and Mach Medical Open New Headquarters

SITES Medical and Mach Medical New Headquarters / Courtesy of SITES Medical and Mach Medical

SITES Medical and its sister company Mach Medical have announced the official opening of their new headquarters facility in Columbia City, Indiana. According to the companies, the facility is equipped with high velocity, single piece flow manufacturing capability which can help orthopedic OEMs (original equipment manufacturers) reduce their inventory by up to 83% and cost of goods by as much as 48%.

"We are thrilled to be operating in our new facility", said Steve Rozow, co-founder and general manager of Mach Medical. "A custom-designed building with an open floorplan gives us the flexibility to configure equipment and working groups as needed over time."

Greg Stalcup, CEO and founder of SITES Medical and co-founder of Mach Medical, added, "Our new facility gives us the space we need to continue to grow and deliver on our mission. We are grateful to a host of partners who have helped us realize this key milestone in our evolution, including Weigand Construction, Design Collaborative, the Indiana Economic Development Corporation (IEDC) and Whitley County EDC."

Compressed lead times, less inventory…

As Steve Rozow explained to *OTW*, these investments will benefit orthopedic OEMs in several ways, most of which increase the speed and quality of component fabrication. "High velocity single-piece flow manufacturing helps orthopedic OEMs reduce their inventory by making and delivering only the component sizes needed for a given patient in time for their surgery."

"With high velocity manufacturing, lead times as short as three weeks are accommodated. This approach enables orthopedic OEMs to vastly reduce their inventory from the estimated 12 months on hand that they typically carry down to two or three months. That said, we also understand that some OEMs aren't quite ready to migrate to this approach, so we also offer highly efficient batch process manufacturing."

…with higher performance, tighter tolerance, more affordable components

"There are several technologies that contribute to the high velocity single-piece flow capability developed by Mach Medical and sister company, SITES Medical. The first is OsteoSync Ti, a high performance, lower cost porous ingrowth material that is applied early in the manufacturing process and is robust enough to withstand automated handling and the uniform and open pore structure makes it easy to clean."

"The second is a dimensional stabilization process that greatly reduces the potential for dimensional movement of the part outside the tolerance band during manufacturing, enabling consistent process flow with no time-consuming and costly off-line rework and inspection required. Additional technology enablers include zero-setup processes, common fixturing, automated transfer systems, digital online inspection and other state-of-the-art manufacturing techniques." — *EH*

Konica Minolta, Medovate Partner for Anesthesia Safety

Konica Minolta Healthcare Americas Inc. and Medovate Ltd are teaming up to promote Medovate's SAFIRA regional anesthesia injection with Konica Minolta's range of ultrasound-guided procedures in the United States.

Courtesy of Konica Minolta and Medovate Ltd

SAFIRA or Safer Injection for Regional Anesthesia is a medical device designed to limit injection pressure and automatically stop injection at high pressure. The design is meant to reduce the risk of nerve injury and advance patient safety.

Studies have shown that regional anesthesia improves post-operative analgesia, cuts down on opioid consumption and anesthesia-related side effects. It also decreases length of stay, early rehabilitation and creates higher patient satisfaction than typically found with general anesthesia.

Both the American Society of Regional Anesthesia and Pain Medicine and the European Society of Regional Anesthesia and Pain Therapy recommend regional anesthesia over general anesthesia for COVID-19 patients where possible to reduce virus transmission.

This new partnership is a part of Konica Minolta's UGPro Solution which combines education, procedures, and imaging equipment to expand the use of regional anesthesia.

"Regional anesthesia delivers numerous benefits for patients, physicians and hospitals, propelling its growth as an important alternative to general anesthesia," said Eric Sumner, executive vice president of ultrasound sales at Konica Minolta.

"Medovate brings a unique combination of clinical innovation and expertise through its association with the United Kingdom's National Health Service and we are proud to partner with them in this endeavor. Both Konica Minolta and Medovate are committed to promoting safer regional anesthesia with solutions that deliver clinical efficiency, simplify use and advance better outcomes for patients."

Konica Minolta's SONIMAGE HS2 System has an advanced algorithm, Simple Needle Visualization, which enhances needle visibility and improves accuracy of needle placement in ultrasound-guided regional anesthesia. The sensitivity of needle visualization can also be adjusted for different types of tissues.

Using SAFIRA with the SONIMAGE HS2 system turns the procedure into a one physician job, both companies said. Usually, an assistant is needed "…to inject the anesthetic solution at the required pressure while the anesthesiologist inserted the needle tip using ultrasound guidance."

"Delivering best practices in regional anesthesia by creating value through innovation is a common vision uniting Medovate and Konica Minolta," said Chris Rogers, sales and marketing director at Medovate.

"As a leading ultrasound manufacturer, physicians make informed decisions at the point-of-care to enhance patient safety, satisfaction, and their clinical experience. We are honored to partner with them to advance the importance and safety of ultrasound-guided techniques for regional anesthesia." — *TR*

EXTREMITIES

More Data Supporting Tranexamic Acid, Now for Shoulder Surgeries

Using tranexamic acid during any type of shoulder surgery can effectively reduce perioperative bleeding, a new study finds.

In the study, "Clinical Effectiveness of Intraoperative Tranexamic Acid Use in Shoulder Surgery: A Systematic Review and Meta-analysis," published online on January 21, 2021 in *The American Journal of Sports Medicine*, researchers measured the effectiveness of tranexamic acid on bleeding and non-bleeding related outcomes in all types of shoulder surgeries. They included both open and arthroscopic procedures.

Source: Unsplash and Olga Kononenko

"Tranexamic acid (TXA) is widely used across surgical specialties to reduce perioperative bleeding. It has been shown to be effective in spinal surgery and lower limb arthroplasty. Among all languages, there are no systematic reviews or meta-analyses investigating its clinical effectiveness for all types of shoulder surgery," the study authors wrote.

The systematic review and meta-analysis included all randomized controlled trials evaluating the use of tranexamic acid against placebo in all

types of shoulder surgery. The primary outcome was total blood loss.

Overall, eight randomized controlled trials were included in the systematic review. Data from seven of the studies were pooled in the meta-analysis.

Pooled analysis showed a significant reduction in two of three outcomes measuring perioperative bleeding with tranexamic acid compared with controls. Estimated total blood loss was mean difference, -209.66 mL; 95% CI, -389.11 to -30.21; p = .02). Postoperative blood loss as measured by drain output was mean difference, -84.8 mL; 95% CI, -140.04 to -29.56; p = .003). Hemoglobin reduction was reduced but not by a statistically significant amount.

"This systematic review and meta-analysis indicated that TXA was effective in reducing blood loss in shoulder surgery. Larger randomized controlled trials with low risk of bias for specific surgical shoulder procedures are required," the authors wrote.

"TXA can be used across shoulder surgery to reduce perioperative blood loss. The use of tranexamic acid may have other beneficial features, including reduced postoperative pain and reduced operative time." — *TR*

LARGE JOINTS

Ultrasound-Guided Hip Injection Improves FAI Diagnosis

The use of ultrasound and ultrasound-guided hip injection can improve the accuracy of diagnosing femoroacetabular impingement (FAI) with atypical symptoms, a new study finds.

In the study, "Ultrasound and Ultrasound-Guided Hip Injection Have High Accuracy in the Diagnosis of Femoracetabular Impingement With Atypical Symptoms," published online in the January 2021 issue of the journal *Arthroscopy*, the researchers evaluated consecutive patients diagnosed with femoroacetabular impingement with atypical symptoms who underwent ultrasound-guided hip injection between January 2017 and February 2019.

Source: Pixabay and Falco

All the patients had a physical examination, ultrasound examination, magnetic resonance imaging (MRI) examination and ultrasound-guided injection before surgery. All the patients who had a positive response to ultrasound-guided hip injection were recommended to undergo arthroscopic surgery.

Sensitivity, specificity, accuracy, and positive predictive value of ultrasound and MRI were all calculated. The researchers also recorded the accuracy of ultrasound-guided hip injection as well as preoperative and postoperative patient-reported outcomes including Visual Analog Scale for pain and modified Harris Hip Score.

Overall, there were 78 patients included in the study and 50 patients had responses to the injection and 36 ended up having arthroscopic surgery.

The response to the ultrasound-guided intra-articular injection was 91.7% accurate for detecting the presence of intra-articular abnormality. No complications from the injection were reported. The sensitivity, positive predictive value, and accuracy by ultrasound diagnosis of cam impingement were 82.9%, 96.7% and 80.6%, respectively. The sensitivity and accuracy by ultrasound diagnosis of anterosuperior labral tear were both 72.2%.

For MRI diagnosis of cam impingement, the sensitivity, positive predictive value, and accuracy were 72.2%, 96.3% and 74.3%, respectively. For MRI diagnosis of labral tear, the sensitivity and accuracy were both 88.9%.

Overall, 34 patients had achieved at least minimal clinically important difference and 33 patients reached the patient acceptable symptomatic state.

"Ultrasound and ultrasound-guided hip injection have high accuracy in the diagnosis of femoroacetabular impingement with atypical symptoms," the researchers wrote. — *TR*

LEGAL & REGULATORY

Full-End Plate Cervical Cage Cleared by FDA

Courtesy of NGMedical GmbH

German medical device maker, NGMedical, Inc., has received its first FDA 510(k) clearance.

The January 28, 2021 clearance is for the company's 3-D printed titanium

cervical BEE cage. The company says the cage's honeycomb structure allows for bony ingrowth and "demonstrates the reduced use of titanium minimizing risks of X-ray artifacts."

In a February 3, 2021 announcement, the company also claims, "another significant innovation from the team, who invented the first line of additive manufactured interbody devices." NGMedical evolved out of Advanced Medical Technologies AG, which was acquired by Medtronic Inc. in 2012.

Intended Use

The cages, according to the FDA clearance documents, are intended for intervertebral body fusion in skeletally mature patients "for the treatment of cervical disc degeneration and/or cervical spinal instability as confirmed by imaging studies (radiographs, CT, MRI) that results in radiculopathy, myelopathy and/or pain at one or two contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment."

BEE Cage

The documents also state that the tapered nose design "provides ease of insertion" while the convex superior and flat inferior surfaces "replicate the patient's vertebral anatomical architecture for maximum surface contact."

The cage's cranial and caudal surfaces have a honeycomb geometry that accepts packing of bone graft to help facilitate bony integration. The device consists of implants available in two widths, one depth, seven heights, and three lordotic angles.

The cages are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.

Lengthy FDA Scrutiny

The primary predicate device was another German cage, the EIT Cellular Titanium Cervical Cage from EIT Emerging Implant Technologies GmbH. It took the agency almost a full year to clear the device. Josh Sandberg, the company's U.S. representative told *OTW* the reason for the lengthy FDA review was due to the cage's full-end plate coverage design.

He added that the cage "addresses every key metric including anatomical design for bony fusion, maximum porosity with improved imaging and increased surface area minimizing subsidence." — *WE*

REIMBURSEMENT

AAOS Guide to Manage Alternate Payment Risks

The American Academy of Orthopaedic Surgeons (AAOS) wants to help you understand and successfully navigate the growing value-based payment landscape. To that end, the organization has developed an 18-page value-based care continuum (VBCC) guide to help your practice evaluate the various alternate payment models (APM) created by payers to achieve value-based care.

Click here for the guide.

The guide notes that providers who rely on fee-for-service and other retrospective payments during the COVID-19 pandemic, "are experiencing significant financial strain, since payment is made following the delivery of a specific service,

Value-Based Care Guide / Courtesy of American Academy of Orthopaedic Surgeons

vs. upfront management of a patient population." A mix of prospective and retrospective payment sources "buffers a practice against the risk of a sudden rise or drop in utilization and creates more stability for practice finances."

The Academy hopes the guide will help you identify where your practice's existing payment arrangements fall along the continuum, understand the transition sought by payers to value-based care, and plan for continued changes in APM contracting arrangements.

In short, the guide helps you identify your risks and opportunities.

The typical assessment of an APM along the continuum, states the guide, "is the level of risk and opportunity that is involved for providers. The greater the opportunity for both financial gains and losses, typically the further along the continuum a given APM is found."

Defining Cost, Quality and Value

Defining cost, quality and value is the key to finding your practice's place along the continuum. So, the guide starts with clearing up confusion as various stakeholders have different definitions for the same terms used in a clinical setting.

The guide creates a "universal lens for interpreting this landscape. With the recent COVID pandemic, newer models that incorporate prospective (payment in advance of a service) may better insulate practices for the future."

For example, here is how the Academy outlines a clear definition of cost, quality and value:

Quality

- Is the successful delivery of appropriate, evidence-based musculoskeletal health care in an effort to achieve sustained patient-centered improvements in health outcomes and quality of life
- Is exemplified by a physician-led musculoskeletal team focused on the individual patient's preference in the delivery of care that is safe, accessible, equitable, and timely
- Fosters evidence-based innovations essential for the advancement of professional and scientific knowledge.

Value

- The relationship of a patient-centered health outcome to the total cost required to reach that outcome, given that care is:
- evidence-based
- appropriate
- timely
- sustainable
- occurs throughout a full cycle of musculoskeletal care for a patient's condition.

Cost

- An investment and includes consideration of greater lifestyle and economic impacts.

Controlling Risk

Finally, knowing what risks are controllable can increase your likelihood of success before engaging an APM. Based on the size and scope of your practice, certain types of risk are more controllable than others. The AAOS strongly recommends that providers "focus on performance risk where they can have the most control and greatest impact." — *WE*

SPORTS

ACL, Hamstring Injuries More Common in Asian Football

Professional Asian football players have a higher rate of anterior cruciate ligament (ACL) ruptures and hamstring injuries than European football athletes, according to a new study.

Source: Pixabay and S. Hermann & F. Richter

In "Injury and illness epidemiology in professional Asian football: lower general incidence and burden but higher ACL and hamstring injury burden compared with Europe," published online on January 5, 2021 in *The British Journal of Sports Medicine*, the researchers analyzed injury and illness epidemiology in professional Asian football.

They followed prospectively teams from the Asian Football Confederation league for three consecutive seasons, 2017 through 2019. Overall, there were 13 teams per season, 322 team months. The researchers collected data on time-loss injuries and illnesses as well as individual match and training exposures.

During the three consecutive seasons, the athletes had 232,665 hours of exposure (88.6% training and 11.4% matches) and sustained 1,159 injuries. About 496 of the injuries occurred during matches and 610 during training. Thirty-two injuries were reported "not applicable" and for 21 injuries data was missing.

Injury incidence was greater during match play (19.2±8.6 injuries per 1000 hours) than training (2.8±1.4; $p < 0.0001$). Overall incidence was 5.1±2.2.

The injury burden was also greater for match injuries than it was for training injuries (456±336 days per 1,000 hours vs. 54±34 days; $p < 0.0001$).

Complete ACL ruptures with 0.14 injuries (95% CI 0.9 to 0.19) and 29.8 days lost, and hamstring strains with 0.86 injuries (0.74 to 0.99) and 17.5 days lost were responsible for the greatest burden.

The researchers also reported that 9.9% of all injuries were reinjuries.

Index injuries caused 22.6±40.8 days of absence compared with 25.1±39 for reinjuries ($p = 0.62$). There were also 175 illnesses recorded which led to 1.4±2.9 days of time loss per team per month.

"Professional Asian football is characterized by an overall injury incidence similar to that reported from Europe, but with a high rate of ACL ruptures and hamstring injury, warranting further investigations," the researchers wrote. — *TR*

ROBIN YOUNG
Ortho Recruiters

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