# BioWorld MedTech

Clarivate Analytics

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Actionable Intelligence • Incisive Analysis

October 16, 2017
Volume 21, No. 200

'New chapter' in MR imaging

## Siemens wins FDA nod for 7T MRI clinical device

*By Katie Pfaff, Staff Writer*

Siemens Medical Solutions Inc. received FDA 510(k) premarket clearance for its Magnetom Terra seven tesla (7T) MRI system, the first to be available for clinical use in the U.S. The device is powered with more than twice the magnetic field strength of the current strongest MRI in a 3T system, enhancing the ability to image structures.

"The overall image quality of MRI improves with higher magnetic field strength," said Robert Ochs, director, division of radiological health, Center for Devices and Radiological Health, FDA, following

See Siemens, page 5

## Inside



End of IPO drought?

## A trio of med-tech companies price IPOs

*By Stacy Lawrence, Staff Writer*

Despite the fact that major medical device companies have seen incredible stock market performance this year– there's been a dearth of medtech IPO offerings. But just this week, a trio of med-tech companies priced IPOs that raised substantial sums and, most importantly to investors, each started out on an upswing once they started trading.

Yardley, Pa.-based Optinose Inc., which has a novel exhalation-based intranasal drug delivery system, raised a whopping $120 million, while children's orthopedic device player

See IPOs, page 6

Firm also focused on DES

## Elixir shows resolve with Desolve, will push forward in bioresorbable space

*By Omar Ford, Staff Writer*

Elixir Medical Corp. remains committed to developing technology for the bioresorbable stent space despite Abbott Laboratories Inc. and Boston Scientific Corp. scaling back on participation in the market. The Sunnyvale, Calif.-based stent maker said its Desolve Absorbable stent is part of a two-prong approach in treating adaptive remodeling. The other component is its Dynamx metallic drug-eluting stent (DES). The firm will release data on both devices during the upcoming

See Elixir, page 7

Diagnostics left behind

## Radiologists challenge value-based model for health care reimbursement

*By John Brosky, Contributing Writer*

PARIS – The shift to value-based health care (VBH) is accelerating with the first implementations by health care systems based on the sets of standards developed by International Consortium for Health Outcomes Measurement (ICHOM), which is based in Cambridge, Mass.

To date, the group has published 21 Standard Sets, covering almost half of what it defines as the global disease burden.

Yet diagnostic tests, and significantly radiology

See Diagnostics, page 8

## Drawn out Senate inquiry over Australia's prostheses list brings little change

*By Tamra Sami, Staff Writer*

PERTH, Australia – Australia's medical device industry welcomed the government's response to the Senate inquiry on the country's prostheses list. But it appears the drama is far from over.

Lack of transparency in how pricing decisions

See Australia, page 9

## Appointments and advancements

Bioprinting start up, focusing on creating a transplantable human heart, **Biolief4d,** of Chicago, appointed Jeffrey Morgan as CMO, and Raimond Winslow to scientific advisory team, both adding to the leadership team's expertise. Morgan brings his experience in thoracic and cardiac surgery, and Winslow is experienced in computational medicine and biomedical engineering.

Scottsdale, Ariz.-based **Styr Labs**, an AI and wearable technology firm, appointed Pete Plamann as president. Plamann will bring experience in development and implementation to head the firm's growth and expansion.

## Financings

San Diego-based **Tandem Diabetes Care Inc.,** maker of touchscreen insulin pumps, reported pricing of an underwritten public offering of 4.63 million shares of its common stock, series A warrants to purchase 4.63 million common stock shares, and series B warrants to purchase 4.63 million common stock shares, for gross proceeds of about $16.2 million, at a public offering price of $3.50 per share and accompanying warrants. Series A and B warrants are immediately exercisable, and will expire at five years, or six months from issuance, respectively. Tandem will use the funds to add working capital, and for general counsel. The offering is expected to close on or about Oct. 17, subject to customary closing conditions. Oppenheimer & Co. Inc. is book-running manager for the offering. National Securities Corp. is co-manager in connection with the offering.

## Product briefs

**Epic Sciences Inc**., of San Diego, along with researchers at the MD Anderson Cancer Center have recently published their findings on androgen receptor (AR) protein expression in circulating tumor cells (CTCs) in patients with metastatic breast cancer in *PLOS One*. The publication, the most comprehensive today in characterizing the AR protein in CTCs of patients with breast cancer, identifies subclonal heterogeneity of AR protein. In recent clinical trials, AR signaling inhibitors, Zytiga and Xtandi, approved in metastatic prostate cancer, have demonstrated potential benefits in a portion of women with metastatic breast cancer. However, current tools to identify patients who may benefit from AR signaling inhibitors are invasive and suffer from accuracy errors in predicting patient response. In addition to profiling CTCs for AR, estrogen receptor and HER2 biomarkers were also characterized. Protein biomarker heterogeneity was observed in many patients. To support the hypothesis of tumor heterogeneity, single cell genomic profiling identified genomic heterogeneity associated with the protein heterogeneity which has been identified as a resistance marker in cancer.

Reno, Nev.-based **The Orthopedic Implant Co.** launched its OIC external fixation system, which allows for bar-to-bar or bar-to-pin construction and has a multihole clamp option with straight and bent posts, at the 2017 annual meeting of the Orthopedic Trauma Association in Vancouver, British Columbia. The single clamp system includes 5 millimeter self-tapping and blunt half-pins and contains carbon fiber bars.

Amsterdam, the Netherlands-based **Royal Philips NV** won FDA 510(k) clearance to market its eL18-4 transducer for 'small parts' assessment, an ultrasound exam to detect abnormalities in the small organs close to the skin, and to assess musculoskeletal injuries. The Philips ultimate small parts solution features four key elements: the eL18-4 Purewave linear array transducer, Philips Microflow imaging, Philips Elastography and Philips precision biopsy. It will be unveiled at the 16th World Federation for Ultrasound in Medicine and Biology congress in Taipei.


# BioWorld MedTech

BioWorld MedTech (ISSN# 1541-0617) is published every business day by Clarivate Analytics.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement.





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# BioWorld MedTech stock report for public med-tech companies

| Company | Symbol | Close 10/06 | Close 10/13 | Change Week | Change YTD | Vol (000) |
|---|---|---|---|---|---|---|
| Abaxis | ABAX | 46.65 | 45.96 | -1.48 | -12.91 | 393 |
| Abbott Labs | ABT | 55.00 | 54.44 | -1.02 | 41.73 | 27209 |
| Abiomed | ABMD | 174.88 | 172.66 | -1.27 | 53.23 | 1447 |
| Accelerate Dx | AXDX | 22.20 | 20.45 | -7.88 | -1.45 | 2824 |
| Accuray | ARAY | 4.45 | 4.15 | -6.74 | -9.78 | 4349 |
| Agilent Tech | A | 66.36 | 66.62 | 0.39 | 46.22 | 7730 |
| Align Tech | ALGN | 187.04 | 192.46 | 2.90 | 100.21 | 3940 |
| Allergan | AGN | 206.75 | 206.61 | -0.07 | -1.62 | 11508 |
| Allied Healthcare | AHPI | 2.15 | 2.01 | -6.51 | 0.42 | 161 |
| Allscripts | MDRX | 14.39 | 13.89 | -3.47 | 36.04 | 6406 |
| Alphatec | ATEC | 3.18 | 3.71 | 16.67 | 15.58 | 1780 |
| Analogic | ALOG | 83.3 | 82.7 | -0.72 | -0.30 | 374 |
| Angiodynamics | ANGO | 17.03 | 16.57 | -2.70 | -1.78 | 850 |
| Anika Therapeutics | ANIK | 59.54 | 59.47 | -0.12 | 21.47 | 364 |
| Antares Pharma | ATRS | 3.89 | 3.94 | 1.29 | 69.10 | 18566 |
| Apollo Endosurg | APEN | 5.47 | 5.33 | -2.56 | -56.17 | 102 |
| Athenahealth | ATHN | 124.02 | 120.47 | -2.86 | 14.55 | 1577 |
| Atricure | ATRC | 23.44 | 22.43 | -4.31 | 14.61 | 617 |
| Atrion | ATRI | 666.6 | 664.9 | -0.26 | 31.09 | 24 |
| Axogen | AXGN | 18.65 | 18.5 | -0.80 | 105.56 | 1057 |
| Baxter Intl | BAX | 62.91 | 62.01 | -1.43 | 39.85 | 10897 |
| Becton Dickinson | BDX | 198.08 | 197.51 | -0.29 | 19.31 | 4434 |
| Biocept | BIOC | 1.29 | 1.26 | -2.33 | 62.58 | 938 |
| Biolife Solutions | BLFS | 5.75 | 5.57 | -3.13 | 245.90 | 394 |
| Bioptix | BIOP | 7.40 | 9.24 | 24.86 | 140.63 | 7840 |
| Bio-Rad Labs | BIO | 226.26 | 223.77 | -1.10 | 22.76 | 575 |
| Biotelemetry | BEAT | 33.20 | 32.25 | -2.86 | 44.30 | 1509 |
| Boston Scientific | BSX | 29.50 | 29.27 | -0.78 | 35.32 | 16463 |
| Bovie Medical | BVX | 3.41 | 3.34 | -2.05 | -6.96 | 255 |
| Bruker | BRKR | 30.41 | 30.61 | 0.66 | 44.52 | 1381 |
| C.R. Bard | BCR | 322.00 | 321.58 | -0.13 | 43.14 | 1855 |
| Cancer Genetics | CGIX | 2.72 | 2.7 | -0.74 | 100.00 | 338 |
| Cantel Medical | CMD | 97.28 | 95.07 | -2.27 | 20.72 | 823 |
| Cardinal Health | CAH | 65.88 | 65.82 | -0.09 | -8.55 | 12665 |
| Cardiovascular Sys | CSII | 28.94 | 28.49 | -1.55 | 17.68 | 632 |
| Caredx | CDNA | 5.62 | 5.9 | 4.98 | 118.52 | 3034 |
| CAS Medical Sys | CASM | 0.91 | 0.87 | -4.40 | -45.96 | 83 |
| Cellectar Biosci | CLRB | 1.72 | 1.92 | 11.63 | 57.38 | 3457 |
| Cerus | CERS | 3.02 | 3.02 | 0.00 | -30.57 | 5496 |
| Check Cap | CHEK | 1.94 | 1.94 | 0.00 | -17.45 | 75 |
| Chembio Dx | CEMI | 6.30 | 6.35 | 0.79 | -6.62 | 33 |
| Cogentix Medical | CGNT | 3.11 | 3.01 | -3.22 | 49.75 | 449 |
| Conformis | CFMS | 4.13 | 3.74 | -9.44 | -53.83 | 786 |
| Conmed | CNMD | 54.24 | 52.18 | -3.80 | 18.13 | 506 |
| Cooper Companies | COO | 241.33 | 237.52 | -1.58 | 35.78 | 1940 |
| Corindus Vascular | CVRS | 1.48 | 1.49 | 0.68 | 113.34 | 1560 |
| CRH Medical | CRHM | 2.60 | 2.65 | 1.92 | -49.52 | 489 |
| Cryolife | CRY | 23.65 | 20 | -15.43 | 4.44 | 2400 |
| Cutera | CUTR | 43.75 | 43.35 | -0.91 | 149.86 | 627 |
| Cytosorbents | CTSO | 6.15 | 6.35 | 3.25 | 16.51 | 813 |
| Danaher | DHR | 87.63 | 86.96 | -0.76 | 11.72 | 8909 |
| DarioHealth | DRIO | 1.92 | 1.86 | -3.12 | -42.77 | 54 |
| Daxor | DXR | 5.12 | 4.97 | -2.93 | -39.70 | 26 |
| Dentsply Intl | XRAY | 58.51 | 58.22 | -0.50 | 0.85 | 8014 |
| Dexcom | DXCM | 47.74 | 47.2 | -1.13 | -20.94 | 7776 |
| Digirad | DRAD | 2.60 | 2.65 | 1.92 | -47.00 | 1462 |
| Dynatronics | DYNT | 2.40 | 2.35 | -2.08 | 0.00 | 61 |
| Edap Tms | EDAP | 3.25 | 3.23 | -0.62 | -1.52 | 343 |
| Edwards Lifesci | EW | 111.46 | 110.47 | -0.89 | 17.90 | 4872 |
| Ekso Bionics | EKSO | 1.20 | 1.20 | 0.00 | -69.85 | 4885 |
| Electromed | ELMD | 7.19 | 7.36 | 2.36 | 89.69 | 105 |
| Endologix | ELGX | 5.73 | 5.09 | -11.17 | -11.01 | 3668 |

| Company | Symbol | Close 10/06 | Close 10/13 | Change Week | Change YTD | Vol (000) |
|---|---|---|---|---|---|---|
| Entellus Medical | ENTL | 20.3 | 19.75 | -2.71 | 4.11 | 766 |
| Enteromedics | ETRM | 2.05 | 1.92 | -6.34 | -4.00 | 3038 |
| Enzo Biochem | ENZ | 10.44 | 10.55 | 1.05 | 52.02 | 468 |
| Exactech | EXAC | 33.90 | 33.55 | -1.03 | 22.89 | 110 |
| Fluidigm | FLDM | 4.71 | 4.62 | -1.91 | -36.54 | 737 |
| Fonar | FONR | 30.70 | 30.95 | 0.81 | 61.62 | 189 |
| Foundation Med | FMI | 46.90 | 45.00 | -4.05 | 154.24 | 887 |
| Fresenius Medical | FMS | 48.94 | 48.26 | -1.39 | 14.33 | 803 |
| Genmark Dx | GNMK | 9.74 | 9.18 | -5.75 | -25.00 | 1628 |
| Genomic Health | GHDX | 33.04 | 32.54 | -1.51 | 10.72 | 544 |
| Glaukos Corp | GKOS | 33.59 | 32.25 | -3.99 | -5.98 | 1789 |
| Globus Medical | GMED | 31.22 | 29.30 | -6.15 | 18.10 | 4050 |
| Grifols | GRFS | 21.12 | 21.26 | 0.66 | 32.30 | 1758 |
| Haemonetics | HAE | 46.31 | 46.20 | -0.24 | 14.93 | 2475 |
| Halyard Health | HYH | 46.04 | 44.64 | -3.04 | 20.71 | 1478 |
| Henry Schein | HSIC | 80.99 | 80.67 | -0.40 | 6.35 | 4440 |
| Hill-Rom | HRC | 77.38 | 77.17 | -0.27 | 37.46 | 2553 |
| Hologic | HOLX | 37.69 | 36.66 | -2.73 | -8.62 | 12350 |
| HTG Molecular Dx | HTGM | 1.88 | 1.90 | 1.06 | -15.18 | 3433 |
| Icad | ICAD | 4.59 | 4.62 | 0.65 | 42.81 | 202 |
| ICU Medical | ICUI | 191.85 | 187.05 | -2.50 | 26.94 | 453 |
| Idexx Labs | IDXX | 158.97 | 158.08 | -0.56 | 34.80 | 1605 |
| Illumina | ILMN | 204.18 | 206.69 | 1.23 | 61.43 | 2819 |
| Inogen | INGN | 94.68 | 93.66 | -1.08 | 39.44 | 749 |
| Inovio Pharma | INO | 6.65 | 6.29 | -5.41 | -9.37 | 5820 |
| Insulet | PODD | 58.83 | 60.93 | 3.57 | 61.70 | 2224 |
| Integer | ITGR | 53.15 | 53.65 | 0.94 | 82.17 | 564 |
| Integra Lifesci | IART | 51.51 | 49.59 | -3.73 | 15.61 | 2260 |
| Interpace Dx | IDXG | 1.62 | 1.60 | -1.23 | -63.64 | 15493 |
| Intersect ENT | XENT | 30.65 | 28.40 | -7.34 | 134.71 | 1116 |
| Intuitive Surgical | ISRG | 361.47 | 360.29 | -0.33 | 70.44 | 3343 |
| Invacare | IVC | 14.75 | 14.05 | -4.75 | 7.66 | 2726 |
| Invitae | NVTA | 9.89 | 9.80 | -0.91 | 23.43 | 1082 |
| Invivo Therapeut | NVIV | 1.65 | 1.50 | -9.09 | -64.29 | 821 |
| Invuity | IVTY | 9.30 | 8.80 | -5.38 | 53.04 | 143 |
| Iradimed | IRMD | 10.40 | 10.20 | -1.92 | -8.11 | 36 |
| Irhythm | IRTC | 50.72 | 50.60 | -0.24 | 68.67 | 1191 |
| Iridex | IRIX | 9.94 | 9.63 | -3.12 | -31.51 | 47 |
| K2M Group | KTWO | 21.78 | 18.76 | -13.87 | -6.39 | 9760 |
| Labcorp | LH | 151.65 | 149.6 | -1.35 | 16.53 | 2350 |
| Landauer | LDR | 67.30 | 67.55 | 0.37 | 40.44 | 470 |
| Lantheus Holdings | LNTH | 18.15 | 17.85 | -1.65 | 107.56 | 1826 |
| Lemaitre Vascular | LMAT | 38.46 | 37.11 | -3.51 | 46.45 | 383 |
| Lianluo Smart | LLIT | 1.30 | 1.320 | 1.54 | -12.00 | 17 |
| Livanova | LIVN | 74.24 | 74.99 | 1.01 | 66.76 | 1878 |
| Luminex | LMNX | 20.56 | 20.55 | -0.05 | 1.58 | 650 |
| Masimo | MASI | 87.14 | 85.01 | -2.44 | 26.13 | 1259 |
| Mazor Robotics | MZOR | 50.17 | 54.07 | 7.77 | 146.67 | 3279 |
| Medtronic | MDT | 79.81 | 78.07 | -2.18 | 9.60 | 40317 |
| Meridian Biosci | VIVO | 14.70 | 14.70 | 0.00 | -16.95 | 846 |
| Merit Medical Sys | MMSI | 45.35 | 42.70 | -5.84 | 61.13 | 1759 |
| Mesa Labs | MLAB | 153.29 | 149.93 | -2.19 | 22.14 | 87 |
| MGC Dx | MGCD | 8.71 | 8.93 | 2.53 | 13.18 | 15 |
| Microbot Medical | MBOT | 1.31 | 1.29 | -1.53 | -78.85 | 9476 |
| Micron Solutions | MICR | 3.65 | 3.64 | -0.27 | -4.21 | 14 |
| Mimedx Group | MDXG | 12.13 | 13.20 | 8.82 | 48.98 | 17168 |
| Myomo | MYO | 5.59 | 3.95 | -29.34 | -46.62 | 264 |
| Nanostring Tech | NSTG | 16.18 | 11.04 | -31.77 | -50.49 | 3080 |
| Natera | NTRA | 14.31 | 13.21 | -7.69 | 12.81 | 691 |
| Natus Medical | BABY | 40.45 | 40.30 | -0.37 | 15.80 | 1951 |
| Neovasc | NVCN | 1.57 | 1.60 | 1.91 | -7.51 | 591 |
| Nevro | NVRO | 92.20 | 93.08 | 0.95 | 28.10 | 1012 |

Continues on next page

# BioWorld MedTech stock report for public med-tech companies

Continued from previous page

| Company | Symbol | Close 10/06 | Close 10/13 | Change Week | Change YTD | Vol (000) |
|---|---|---|---|---|---|---|
| Novocure | NVCR | 18.05 | 16.3 | -9.70 | 107.64 | 3802 |
| Nuvasive | NUVA | 56.95 | 50.82 | -10.76 | -24.55 | 9535 |
| Nuvectra | NVTR | 13.44 | 13.96 | 3.87 | 177.53 | 133 |
| Nxstage Medical | NXTM | 27.68 | 27.59 | -0.33 | 5.27 | 3086 |
| Oncocyte | OCX | 5.95 | 6.70 | 12.61 | -4.96 | 77 |
| Opko Health | OPK | 7.00 | 6.95 | -0.71 | -25.27 | 18853 |
| Orasure Tech | OSUR | 22.25 | 21.57 | -3.06 | 145.67 | 1897 |
| Orthofix Intl | OFIX | 50.68 | 48.56 | -4.18 | 34.22 | 372 |
| Oxford Immunotec | OXFD | 16.77 | 16.85 | 0.48 | 12.71 | 261 |
| Pacific Biosci | PACB | 4.88 | 4.47 | -8.40 | 17.63 | 3242 |
| Pavmed | PAVM | 5.23 | 5.02 | -4.02 | -27.25 | 29 |
| Penumbra | PEN | 94.2 | 92.1 | -2.23 | 44.36 | 455 |
| Perkinelmer | PKI | 70.61 | 71.39 | 1.10 | 36.89 | 3659 |
| Presbia | LENS | 5.14 | 4.70 | -8.56 | 34.29 | 37 |
| Pro-Dex | PDEX | 7.30 | 7.25 | -0.68 | 54.26 | 46 |
| Pulse Biosci | PLSE | 18.9 | 24.44 | 29.31 | 276.00 | 770 |
| Quest Dx | DGX | 92.42 | 91.45 | -1.05 | -0.49 | 7057 |
| Quidel | QDEL | 42.96 | 42.86 | -0.23 | 100.09 | 1865 |
| Quotient | QTNT | 5.03 | 5.14 | 2.19 | 6.20 | 958 |
| Radnet | RDNT | 11.45 | 11.25 | -1.75 | 74.42 | 770 |
| Resmed | RMD | 77.25 | 77.63 | 0.49 | 25.11 | 2264 |
| Retractable Tech | RVP | 0.62 | 0.60 | -3.23 | -35.48 | 534 |
| Rewalk Robotics | RWLK | 1.52 | 1.45 | -4.61 | -48.21 | 629 |
| Roka Biosci | ROKA | 0.79 | 1.92 | 143.04 | -54.72 | 39711 |
| Royal Philips NV | PHG | 41.1 | 40.92 | -0.44 | 33.86 | 7499 |
| RTI Surgical | RTIX | 4.75 | 4.70 | -1.05 | 44.62 | 465 |
| Seaspine | SPNE | 11.44 | 10.71 | -6.38 | 35.57 | 77 |
| Second Sight | EYES | 1.15 | 1.14 | -0.87 | -42.13 | 2116 |
| Senseonics | SENS | 3.34 | 2.96 | -11.38 | 10.86 | 3024 |
| Sensus Healthcare | SRTS | 5.29 | 5.69 | 7.56 | 8.38 | 65 |
| Sientra | SIEN | 15.93 | 16.3 | 2.32 | 91.31 | 727 |
| Skyline Medical | SKLN | 1.63 | 1.62 | -0.61 | -42.14 | 690 |
| Smith & Nephew | SNN | 36.61 | 38.50 | 5.16 | 27.99 | 9716 |
| Staar Surgical | STAA | 13.70 | 13.35 | -2.55 | 23.04 | 300 |
| Steris | STE | 90.51 | 89.49 | -1.13 | 32.79 | 1793 |
| Strata Skin Sci | SSKN | 1.78 | 1.84 | 3.37 | -16.36 | 52 |
| Stryker | SYK | 149 | 146.69 | -1.55 | 22.44 | 6073 |
| Surmodics | SRDX | 31.85 | 31.45 | -1.26 | 23.82 | 126 |
| T2 Biosystems | TTOO | 4.47 | 4.21 | -5.82 | -19.96 | 833 |
| Tactile Systems | TCMD | 32.96 | 31.92 | -3.16 | 94.52 | 1019 |
| Tearlab | TEAR | 1.73 | 1.42 | -17.92 | -72.69 | 845 |
| Teladoc | TDOC | 34.35 | 32.15 | -6.40 | 94.85 | 3200 |
| Teleflex | TFX | 246.05 | 238.71 | -2.98 | 48.13 | 985 |
| Thermo Fisher Sci | TMO | 193.21 | 192.42 | -0.41 | 36.37 | 3981 |
| Trinity Biotech | TRIB | 5.35 | 5.26 | -1.68 | -23.99 | 173 |
| Utah Medical | UTMD | 76.7 | 75.3 | -1.83 | 3.51 | 103 |
| Valeritas | VLRX | 2.78 | 2.26 | -18.71 | -54.80 | 65 |
| Varian Medical Sys | VAR | 102.39 | 102.7 | 0.30 | 14.39 | 3051 |
| Veracyte | VCYT | 9.22 | 8.80 | -4.56 | 13.70 | 337 |
| Vericel | VCEL | 4.90 | 4.85 | -1.02 | 61.67 | 4526 |
| Vermillion | VRML | 1.64 | 1.58 | -3.66 | 66.32 | 183 |
| Viewray | VRAY | 6.32 | 5.91 | -6.49 | 88.82 | 1566 |
| Viveve Medical | VIVE | 5.61 | 5.39 | -3.92 | 4.66 | 574 |
| Vocera Comm | VCRA | 31.1 | 29.51 | -5.11 | 59.60 | 577 |
| Volitionrx | VNRX | 2.70 | 2.42 | -10.37 | -47.05 | 233 |
| West Pharma | WST | 95.45 | 95.17 | -0.29 | 12.19 | 1288 |
| Wright Medical | WMGI | 27.51 | 26.33 | -4.29 | 14.58 | 5496 |
| Zimmer Biomet | ZBH | 119.27 | 119.7 | 0.36 | 15.99 | 5241 |

## Notes

Trading volumes for Nasdaq, Amex and NYSE are recorded as the total number of shares traded (in thousands) on a weekly basis (cumulative Monday through Friday); the weekly and YTD changes are from IPO completion, where applicable.

**Average percent change week: -1.01%**
Range: -31.77% to +143.04%; Number of companies: 182
(not market weighted)

**Average percent change year-to-date: +24.57%**
Range: -78.85% to +276%; Number of companies: 182
(not market weighted)

## 10 biggest U.S. gainers for the week

| Share price by percent | | Share price by dollars | |
|---|---|---|---|
| Roka Biosci | 143.04 | Pulse Biosci | 5.54 |
| Pulse Biosci | 29.31 | Align Tech | 5.42 |
| Bioptix | 24.86 | Mazor Robotics | 3.90 |
| Alphatec | 16.67 | Illumina | 2.51 |
| Oncocyte | 12.61 | Insulet | 2.10 |
| Cellectar Biosci | 11.63 | Smith & Nephew | 1.89 |
| Mimedx Group | 8.82 | Bioptix | 1.84 |
| Mazor Robotics | 7.77 | Roka Biosci | 1.13 |
| Sensus Healthcare | 7.56 | Mimedx Group | 1.07 |
| Smith & Nephew | 5.16 | Nevro | 0.88 |

## 10 biggest U.S. losers for the week

| Share price by percent | | Share price by dollars | |
|---|---|---|---|
| Nanostring Tech | -31.77 | Teleflex | -7.34 |
| Myomo | -29.34 | Nuvasive | -6.13 |
| Valeritas | -18.71 | Nanostring Tech | -5.14 |
| Tearlab | -17.92 | ICU Medical | -4.80 |
| Cryolife | -15.43 | Cooper Companies | -3.81 |
| K2M Group | -13.87 | Cryolife | -3.65 |
| Senseonics | -11.38 | Athenahealth | -3.55 |
| Endologix | -11.17 | Mesa Labs | -3.36 |
| Nuvasive | -10.76 | K2M Group | -3.02 |
| Volitionrx | -10.37 | Merit Medical Sys | -2.65 |

## Siemens

Continued from page 1

the clearance. "The added field strength allows for better visualization of smaller structures and subtle pathologies that may improve disease diagnosis."

The FDA granted 510(k) premarket clearance for Malvern, Pa.-based Siemens' Magnetom Terra after comparison to a predicate device.

### 7T MRI indications

Using magnetic fields and radiofrequency to image the body, the MRI system is intended for diagnostic imaging of patients weighing greater than 66 pounds and for use with looking at the head and extremities, according to the FDA. Clearance was determined in "comparison to a predicate device and acquisition of sample clinical images. The agency reviewed the safety of the radiofrequency subsystem through computational modeling, simulations and rigorous experimental validation," shared FDA. A comparative study also was provided by Siemens, which included imaging with the 7T device and a 3T device among 35 patients who were healthy. Radiologists studied the images and determined the 7T device was "of diagnostic quality and, in some cases, an improvement over imaging at the 3T," said FDA.

"The higher the field strength the better the image quality essentially, so this scanner with seven tesla field strength has more than twice the signal-to-noise ratio or clarity of a 3T MR for higher resolution and for faster scanning or faster acquisition times in clinical applications," Murat Gungor, vice president, Magnetic Resonance, Siemens Healthineers North America, told *BioWorld MedTech*. "This added field strength because of its clarity being so superior, it enables much better visualization of smaller structures and pathologies."

Improvement in imaging ultimately can lead to better diagnosis, treatment planning, clinical decision making, and possibly to overall outcome for patients.

### Potential of Magnetom Terra

Gungor called the device a "game changer" and one that leads to new capabilities in clinical imaging.

"The Terra 7T is the first MRI field strength that is above 3T to be cleared for clinical imaging in nearly 20 years," he said. "[Magnetom Terra] enables visualization of previously unseen structures [at lower field strength]. The platform itself just offers a lot to discover. We are opening a brand new chapter in medical imaging, and we have a lot to discover."

The device can provide visualization to 0.2 millimeter in-plane anatomical resolution, explained Gungor, adding that the human hair is 0.1 millimeters in diameter. That imaging capability can "yield never before seen clinical details."

Siemens plans to work with institutions to determine clinical usage and potential future applications for the device, such as oncology or cardiology.

"For us the next step would be to provide this technology to a wide variety of customers in the U.S. and collaborate with these customers to push the boundaries of it," said Gungor.

> *"We are opening a brand new chapter in medical imaging, and we have a lot to discover.*
>
> Murat Gungor
> Vice president, Magnetic Resonance, Siemens Healthineers North America

### Specifications of MRI system

While 7T systems are available for research purposes currently, the Magnetom Terra is updated with 20 percent faster computing power and 50 percent lighter magnets, making the machine more suitable for varied environments.

"Now [that] we have this big component built in a much lighter form, it helps us to easily integrate this unit and install it in clinical environments even on an upper floor of hospitals," said Gungor.

The tool also acts as a recruitment and retention tool, drawing employees to a particular institution as well as increasing the possibility for research grants.

"This is the type of system that can be leveraged by the health care systems to grow their reputations," he said.

Magnetom Terra allows the operator to switch between "clinical mode" for imaging and an investigational "research mode" and stores the images separately. The MRI scanner provides images with as many as 64 receive channels, and 80/200 gradients supply enough power to complete diffusion MRI and functional MRI, and to use Siemen's simultaneous multislice application for advanced neurologic imaging.

Several firms offer MRI with 3T MRI systems, including Amsterdam-based Philips Healthcare's Ingenia 3.0T MR system, Japan-based Toshiba Medical Systems Corp.'s Vantage Titan 3T MRI, and Chicago-based GE Healthcare's Discovery MR750 3.0T and MR750w 3.0T. ♦

# IPOs

Continued from page 1

Orthopediatrics Corp. based in Warsaw, Ind., raised $52 million and hair transplant surgical robotics system company Restoration Robotics Inc. based in San Jose, Calif., raised $25 million.

One measure of medical device sector performance, an exchange traded fund known as iShares US Medical Devices that includes many major public medical device players, is up by more than one-quarter so far this year. And a slew of biotech IPOs have been making it out this fall. But, until now, the med-tech industry has remained largely on the public market sidelines.

"We had actually wanted to go out a year ago. But between Brexit and the uncertainties around the election and the fact that the market had dried up for medical device IPOs, we had to stop. So, we took the plunge several weeks ago. This is the first medical device IPO since something like July of last year, if memory serves, so we have sort of broken the ice," Orthopediatrics President and CEO Mark Throdahl told *BioWorld MedTech*.

"Big institutional investors were suffering with outflows into index funds, and that is the kind of discretionary, marginal capital that they had to invest in new IPOs and it had dried up. So, that has changed as well in the last several months, and we find that the environment is more beneficial now in terms of a company like ours going public."

The Optinose IPO priced on Thursday at the midpoint of its expected range at $16 and traded up to more than $19 around mid-day on Friday, while Orthopediatrics priced on Wednesday also at its estimated range midpoint of $13 rose to about $18.50. Restoration Robotics priced on Wednesday at the low end of its range at $7, but was also up to more than $9 by mid-day Friday trading.

## Role of revenues

All three of these companies are focused on marketing and generating revenues, but none have reached profitability. The IPO financings will go mostly to back commercialization efforts, including allowing Orthopediatrics to build up its hospital consignment offerings for its implants and instrument sets; Optinose to launch its Xhance (fluticasone propionate) nasal spray to treat chronic rhinosinusitis with nasal polyps using its Breath Powered exhalation delivery system (EDS) that is expected in the second quarter of 2018 after an FDA approval came last month; and Restoration Robotics to support the marketing of its minimally invasive ARTAS System, a robotic arm for use in hair restoration surgical dissection that's been FDA-cleared since April 2011 that has been upgraded in recent years with the ability to create a 3-D consultation model as well as incision-making capabilities for implantation.

The Orthopediatrics strategy is an interesting one, particularly in the context of ongoing U.S. hospital consolidation that makes it difficult for smaller companies to gain and hold their position as hospital purchasing groups seek to drive more of medical device purchasing, rather than relying solely upon surgeons. Orthopediatrics seeks to sew up the children's orthopedic market, making it essential to surgeons specializing in this population with very specific needs.

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>
> Mark Throdahl
> President and CEO, Orthopediatrics

"This is a category leadership play where we want to surround our customers with many of the key systems that they use. We want to be the only provider of clinical education programs for young pediatric orthopedic surgeons," said Throdahl. "We are now the leading financial sponsor of the five pediatric orthopedic surgical societies. And all of these things mesh together in a leadership of a category, which I like to say transcends any given technology that we have. And, in my opinion, that is how we build a durable franchise that frankly is built to last."

"Fortunately, there have been very few hospitals where we are frozen out because they have a huge contract with an adult provider, and they don't believe that they should make room for a pediatric provider. In most cases, our surgeons will have discretion to use the systems they want and they want to use FDA-approved systems that their fellow surgeons have helped design for kids rather than use repurposed small stature adult systems," he added.

Orthopediatrics markets 21 surgical systems across trauma and deformity, complex spine and ligament reconstruction procedures, with another six products in development such as a first potential treatment for brittle bone disease and a medial patellofemoral ligament system, which is a frequently injured ligament for kids playing sports. It's also working on smart, adjustable implant systems for early onset scoliosis and limb length discrepancies that expand as patients grow and give precise feedback on how much it has moved.

The company had $21.6 million in revenues during the first half of this year; it expects to breakeven on net income next year and to be cash-flow positive in 2019 or 2020. Orthopediatrics has seen annual revenue growth in excess of 20 percent for each of the last six years.

## After the IPO

Optinose will use its IPO proceeds to launch Xhance in the newly approved indication, as well as to conduct clinical trials

See IPOs, page 10

# Elixir

Continued from page 1

Transcatheter Cardiovascular Therapeutics conference in Denver held Oct. 29 through Nov. 2.

"It is unfortunate the industry believes there is a class effect in bioresorbable stents," Motasim Sirhan, Elixir's founder and CEO, told *BioWorld MedTech*. "We feel very strongly and confident about Desolve's unique early degradation resorption profile achieving early adaptive remodeling, and strong five year clinical data, well beyond the complete resorption of the scaffold."

Sirhan said adaptive remodeling is the phenomenon when the artery expands to compensate for plaque build up (disease progression) thereby continuing to allow adequate blood flow go through the artery.

In May, Elixir released data at the European Association for Percutaneous Cardiovascular Interventions, in Paris, from the DESolve Nx clinical trial. Results of the trial demonstrated that at the five-year endpoint, long after the full bioresorption of the Desolve scaffold, Desolve continues to show a low overall major adverse cardiac events (MACE) rate of 9 percent with no additional clinically indicated target lesion revascularizations from years two through five, and no definite scaffold thrombosis through five years. Results from the trial showed the Desolve scaffold achieves early degradation in six months and near complete resorption of the scaffold mass in one year. The DESolve Nx pivotal trial enrolled 126 patients at 13 centers in Europe, Brazil and New Zealand.

The company has three CE marks surrounding its bioresorbable platform and plans to eventually bring the technology to the U.S.

## Changing Dynamx

Elixir said Dynamx is a 71 microns thin metallic DES. Unlike DES, however, Dynamx allows the vessel to exhibit its normal pulsatile motion and adaptive remodeling capabilities. Elixir said it will be sharing for the first time the concept, design, data from preclinical testing and clinical program for its Dynamx stent at TCT.

The company will begin gathering more stringent data in the near future.

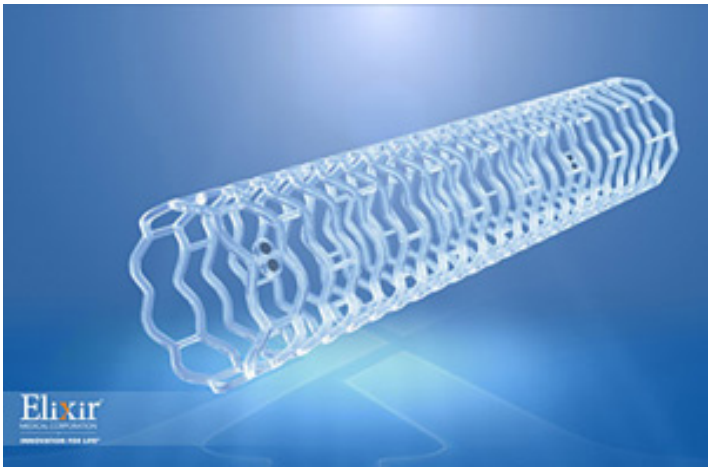
"The clinical trial will start in Europe next month," Sirhan said. "There will be up to 50 patients enrolled in the first trial and subsequently we will conduct a larger randomized clinical trial against leading DES platforms."

Plans eventually call for the company to seek FDA approval for the device.

"We believe that Dynamx will be a transformational technology in percutaneous coronary intervention," he said.

## March madness

In September, Abbott Laboratories said it would stop selling its Absorb bioresorbable vascular scaffold, citing low commercial sales as the reason for the decision. (See *BioWorld MedTech*, Sept. 11, 2017.) The Abbott Park, Ill.-based company first received FDA approval for Absorb in July of 2016. (See *BioWorld MedTech*, July 6, 2016.) The company did note it would continue to work on the next generation of a bioresorbable device.




Desolve stent; Elixir Medical Corp.

> *"The market has not developed as strongly as the industry expected given the clinical shortcomings of the first commercial bioresorbable stents. Despite the headwinds, Elixir is committed to bringing adaptive remodeling products forward because that is what's going to take the standard of care to the next level and potentially expand beyond what DES can do today.*
>
> Motasim Sirhan
> Founder and CEO, Elixir

Problems surrounding Abbott's absorb began to mount in March. First, Abbott revealed it was restricting the use of Absorb in Europe to clinical registries that were being started in order to collect additional real-world data. That same month, the FDA issued a Medwatch alert suggesting Abbott's Absorb carried too high a rate of MACE, at 11 percent, in its two-year ABSORB III study. The rate, which marks endpoint of heart attack, cardiac death or revascularization, was significantly higher when compared to Abbott's Xience DES (7.9 percent MACE). At the same time, the thrombus rate also was higher at 1.9 percent compared to 0.8 for Xience.

Things continued to go downhill for Abbott in March, when the 1,850-patient, Amsterdam Investigator-initiateD Absorb Strategy All-comers Trial (AIDA) was terminated early by the data and safety monitoring board. Results from AIDA showed that Abbott's stent underperformed, failing to deliver better long-term outcomes and reinforcing concerns of increased stent thrombosis, including late stent thrombosis.

See Elixir, page 10

## Diagnostics

Continued from page 1

exams, are excluded from the calculations.

In response, the Vienna, Austria-based European Society of Radiology (ESR) published a paper criticizing the approach and calling for the integration of a value-based radiology (VBR) approach within the VBH framework.

Lorenzo Derchi, chair of the ESR Value-Based Imaging Working Group said, "Within existing VBH frameworks, value measurements start at the beginning of therapy. The whole diagnostic process is disregarded, and is considered only if it is the cause of errors or complications."

"It is still early days," Derchi told *BioWorld MedTech*. "Value-based health care is an economic approach that is interesting, but not the only possible approach. The initiators of this movement come from the Harvard School of Economics, not the medical school."

"Radiology adds impact, more than what is being called value, which is only a calculation of outcome versus cost," said Derchi.

"I use the term impact rather than the word value here because this is the main problem in the ICHOM framework. The impact of the imaging process, or other diagnostic methodologies such as lab tests, the pathology report, or even biopsies, need to be considered as a cost but also as something that adds impact on the outcome, affects the value of what is done in the treatment process," he said.

"It is not easy to value the impact of diagnosis," he said. "It becomes easier for calculations if the diagnosis is taken for granted. It is not clear if ICHOM did not consider diagnostics, or if they considered it but found it too difficult to measure as a value."

VBH started in the United States as a response to ineffective reimbursement models introduced by payers to manage costs of health care services, such fee-for-service or capitated payment approaches.

European governments are also struggling to manage costs in their national health systems, and the ESR paper, published in the October issue of the society's official journal *Insights Imaging*, points out that short-term cost-cutting solutions and austerity measures that have been the first reaction by payers have already reached their limit and are now negatively affecting the quality of health care, creating a vicious circle of increased demands and a need for greater spending.

"It is like Ryan Air. It works for a while, then low-cost becomes a low-value service," said Derchi in the interview at the French Radiology Congress in Paris where he spoke on the need to shift from volume based reimbursement to VBR.

"At ESR, we are evaluating the whole diagnostic process. As we have written, the patient is not a disease. The patient is an individual with problems and a first outcome is to determine the cause of these problems," he said.

Ninety percent of patients who present to a health care provider undergo some type of diagnostic exam, he said. With the availability of advanced technologies, physicians no longer trust themselves to make a diagnosis without the aid of a test.

> *"At ESR, we are evaluating the whole diagnostic process. As we have written, the patient is not a disease. The patient is an individual with problems and a first outcome is to determine the cause of these problems.*
>
> Lorenzo Derchi
> Chair, European Society of Radiology
> value-based imaging working group

For their part, patients expect, and even insist, on undergoing some type of diagnostic exam.

"On one hand we promote the capability of the technology to detect disease, and on the other hand, physicians protect themselves by requesting exams against possible litigation," he said.

"Since we believe that diagnosis is an outcome – an intermediate outcome – we believe we can assess metrics to demonstrate whether the diagnosis is correct or actionable and that it is relevant and useful to the episode of care. As radiologists we have a long tradition of measuring and assessing our chain of work from the request of the referring physician to the report, to measure each step," said Derchi.

VBR creates an opportunity to shift from volume-based calculations to a value-based practice of radiology that puts an emphasis on quality, the topic for his presentation to French radiologists.

"We are doctors in medicine. We are not photographers, nor operators running machines and pushing buttons. We interpret what is coming from the machines to integrate this information into the clinical picture of the patient to develop the diagnosis. It is our medical knowledge that gives these images significance," he said.

"If you measure only volume, then time is squeezed, the time for the examination is tight, cutting the time for reading and interpreting and for communicating the report. There is no longer time to discuss the findings with the referring physician, to be sure they are understood, and how they may change the opinion on how to treat," said Derchi.

"There are two perspectives," he concluded. "One is economic, and if we are to be measured, we want to be able to show that we have impact on value. The other is an opportunity to discuss this topic, to create a moment for rethinking how we can also achieve an emphasis for the quality in our work." ♦

# Australia

Continued from page 1

are made and limited integration between health technology assessment systems and processes remain obstacles in reaching any type of reform for the Prostheses List (PL) framework, according to the Senate Community Affairs Reference Committee report.

Although price cuts on medical devices listed on Australia's Prostheses List have already gone into effect, and more cuts are expected, how to reform the list is still being hammered out.

At issue is the disparity in prices for medical devices for private hospitals versus public hospitals and how prices should be set.

The Australian government introduced the PL in 1985 to regulate the price of prostheses paid by patients with private health insurance to reduce public hospital waiting lists for procedures involving prostheses. Regulated by the Australian government, the PL requires that private patients have no out-of-pocket expenses for prostheses.

The PL enables surgeons to choose the optimal device for patients, and private hospitals purchase prostheses directly from device manufacturers and often receive rebates or other incentives from manufacturers for buying in bulk or achieving certain volume amounts.

When a private patient receives treatment in a public hospital, the public hospital is able to access the prostheses at a much lower price and invoice the private health insurer for the higher minimum benefit amount on the PL.

"The Prostheses List was introduced as a measure to stabilize uncontrolled and uncontained growth in the private sector; however, it resulted in a system that is complicated and not well understood," the Senate committee report says.

For the purposes of the PL, a prostheses is defined as a surgically implantable device such as a cardiac pacemaker, intraocular lenses used in cataract surgery and hip or knee joints used in replacement surgeries. The PL does not include external devices such as hearing aids or prosthetic limbs.

## Price cuts met with angst

Price cuts were announced last year for the PL, which would cut A$86 million in benefits to about 2,500 device manufacturers. When the medical device industry condemned the price cuts, that outcry raised the hackles of the private health insurance industry, which complained that medical devices represent a large percentage of hospital procedures and have driven up costs of private health insurance.

The battle pitted device manufacturers, private health insurance companies and hospitals against each other as each side blamed the other for increasing premiums for private health insurance in Australia.

Private health insurance companies have complained that they pay more – up to $800 million more – than prostheses covered under the public system.

That $800 million figure was a bone of contention throughout the long consultation process. It initially was reported by Private Healthcare Australia (PHA), which represents private health care companies, that a 45 percent decrease in the private prostheses expenditure would amount to roughly $800 million in savings.

This figure was disputed by a number of stakeholders on the grounds that it was based on flawed methodology and data.

For example, the Medical Technology Association of Australia (MTAA) argued that the calculation was made on a very small sample of only 41 of the 10,400 devices listed on the PL. These devices were also from a narrow range of categories on the PL and were devices that were more likely to include additional services and ancillary support.

MTAA's own analysis represented almost 80 percent of the PL expenditure and shows a difference between public and private pricing of medical devices "that is considerably less than what has been claimed by the private health insurance (PHI) industry," the association said in its submission.

The Department of Health was also unable to verify the accuracy of the $800 million savings figure, the report said, and the committee acknowledged the "concerns of stakeholders regarding the veracity of the $800 million in potential savings from reforming the PL. However, the committee believes that there is significant scope for reform and savings in this area."

## Effect on SMEs

In a supplementary submission, a group of Australian owned small and medium enterprises (SMEs) that develop, manufacture and distribute medical devices reported that the recent 7.5 percent price cut to hips and knees on the Prostheses List has already resulted in employee redundancies and cuts to R&D programs.

Global Orthopaedic Technology's top line revenue was slashed by $2.4 million as a result of the price cuts, and the company implemented a hiring freeze and placed a hold on R&D projects, the company reported.

Other device sponsors were critical of the approach taken in the initial targeted review and reduction of prostheses benefits. Biotronik Australia Pty Ltd. said in its comments that the "adhoc cut of 7.5 percent to 10 percent to benefits on the PL based on only a shallow assessment of price structures by the [Industry Working Group and Department of Heath] undertaken in isolation is poor governance as it creates market, and more importantly, patient care dislocation."

MTTA stressed that the benefit reductions were not based on evidence "and arose due to pressure from private insurers to make some savings."

In its report, the committee sided with industry on that lack of evidence, saying the decision by the former Minister for Health to make the cuts and the size of the cuts, "appears to have been made with limited access to sufficient data."

The Senate committee urged the Minister of Health to release new Independent Hospital Pricing Authority (IHPA) data on the differences between protheses prices in private and public hospitals and investigate whether this could be used to adjust PL prices as soon as possible.

See Australia, page 10

## IPOs

Continued from page 6

for an additional one: chronic sinusitis without nasal polyps. It's also in the midst of early stage research to use its EDS device with oxytocin to treat Prader-Willi syndrome and autism spectrum disorder and with orexin-A to treat narcolepsy or Parkinson's disease.

EDS is designed to use the natural functional actions of the upper nasal airways to offer deeper intranasal delivery and better drug deposition than standard nasal spray and aerosol delivery systems. A version of the device is available for both liquid and powder drug formulations.

This med-tech IPO revival may have legs if companies can continue to rack up stock market gains and attract high-quality investors interested in the fundamentals.

Orthopediatrics' Throdahl was optimistic about the IPO investor base his company accrued in the current climate. "We were able to attract a blue-chip series of long investors that one of our bankers characterized as the most impressive IPO book they had seen in a decade. My fear, frankly, in going public was more that we would attract various short-term holders." ♦

## Elixir

Continued from page 7

### Shaky market?

Absorb's string of bad news sent ripple effects throughout the industry, causing Abbott's rival, Boston Scientific, to abandon its bioresorbable stent program back in July. The company – so set on distancing itself from the space – even allowed a distribution agreement with Reva Medical Inc., another bioresorbable stent maker, to expire. (See *BioWorld MedTech*, Aug. 7, 2017.)

A recent report from the European Society of Cardiology (ESC) and European Association of Percutaneous Cardiovascular Interventions (EAPCI) is poised to cause even more shake ups to the space, saying that physicians should use DES over bioresorbable scaffolds. The study, titled "Report of an ESC-EAPCI Task Force on the evaluation and use of bioresorbable scaffolds for percutaneous coronary intervention: executive summary," was published in the Sept. 25, 2017, edition of *Eurointervention*.

Authors of the study said, "Only one device – the Absorb bioresorbable vascular scaffold – has published randomized clinical trial data and this data show inferior outcomes to conventional DES at two to three years. For this reason at present, bioresorbable scaffolds should not be preferred to conventional DES in clinical practice."

Elixir has one of the last stents standing in the bioabsorbale market. Other devices include Biotronik Corp.'s Magmaris; Reva's Fantom; and Terumo Corp.'s Arterial Remodeling Technologies bioresorbable scaffold.

"The market has not developed as strongly as the industry expected given the clinical shortcomings of the first commercial bioresorbable stents," Sirhan said. "Despite the headwinds, Elixir is committed to bringing adaptive remodeling products forward because that is what's going to take the standard of care to the next level and potentially expand beyond what DES can do today." ♦

## Australia

Continued from page 9

MTAA said it welcomed the government report, noting that it was important that "reform and increased transparency is based on facts and not fiction when it comes to evidence."

The government report acknowledges that the IHPA data did not fully take into account differences in the type and use of prostheses in the private and public sectors.

### Back to the drawing board

After months of consultations and stakeholder meetings, the Senate committee recommended that stakeholders start from scratch on new consultations, but this time, with better coordination and more openness.

Various stakeholders identified a number of areas in the PL framework that would benefit from reform; however, the lack of transparency hinders consideration of alternative pricing models.

The committee received 45 submissions from medical device manufacturers, private health insurers, private hospitals, practitioners, consumer groups and government departments.

The committee recommended that the Prostheses List Advisory Committee (PLAC), in consultation with stakeholders, develop and publish a formal work plan with defined agreed targets, activities, timeframes, indicators and outcomes to assist stakeholders to better understand and participate in the reform process.

"The Prostheses List Framework has been subject to a number of reviews since its introduction in 1985," the reports said.

"Successive reviews have consistently raised similar issues, suggesting that there are a number of challenges to reform. However, while the inquiry has shown that there is general support for reform, there is little agreement on the areas which require reform and how this should be achieved."

The Senate committee said the Department of Health should immediately implement more robust coordination between the Therapeutic Goods Administration and the PLAC, including implementing appropriate coordination of HTA processes to ensure that applications to list on the PL have a concurrent application for listing on the Australian Register of Therapeutic Goods.

It also recommended that the Department of Health conduct further analysis to determine the most appropriate benefit setting model, and analysis should include outcomes-based categorization of items on the PL, and the option of the government purchasing devices directly. ♦

## Product briefs

**Vivasure Medical Ltd.**, of Galway, Ireland, reported the successful enrollment of the first patient in the Frontier IV clinical study, a nonrandomized multicenter international trial, designed to expand the indications of its proprietary Perqseal large arteriotomy closure technology. Large arteriotomies (12F+) are vessel punctures created to facilitate endovascular procedures such as transcatheter aortic valve replacement, endovascular aneurysm repair, balloon valvuloplasty and ventricular assist devices.

## Other news to note

**Dermatologistoncall**, a Pittsburgh-based a online dermatology company, and **Clarify Medical Inc.**, San Diego-based developer and marketer of the Clarify Medical Home light therapy system, reported they formed a strategic collaboration to provide light therapy treatment for patients at home, at work or traveling, linked to the patients' physicians through their smartphones. DermatologistOnCall and Clarify Medical plan to begin co-marketing their services in November. Financial and operational aspects of the partnership were not disclosed.

**GE Healthcare**, of Chicago, said it has received Carequality certification to enable seamless data sharing by its ambulatory EHR customers with thousands of hospitals, physician practices, payer networks, vendors and consumer services nationally.

**Inivata Ltd.**, a Cambridge, U.K.-based clinical cancer genomics company, reported it is collaborating with **Genomics England**, to assess the quality of blood plasma samples and explore the potential of liquid biopsy to improve disease management and patient outcomes. In the first phase of a larger pilot, Inivata will analyze plasma samples donated by participants in Genomics England's 100,000 Genomes Project. As well as determining the suitability of plasma, the study will focus on the use of Inivata's liquid biopsy technology, Invision, to discover the mutations in the human genome that can lead to or demonstrate the presence of cancer.

Dublin-based **Medtronic plc** and **Mercy Technology Services**, of St. Louis, reported a data sharing and analysis network collaboration to gather clinical evidence for medical device innovation and patient access. The pair will co-develop methods to address questions about medical device safety and patient outcomes through clinical information captured during routine patient care, and stored as de-identified data. The launch phase will gather data from 80,000 patients with heart failure to explore real-world factors in a patient's response to cardiac resynchronization therapy. The effort aligns with FDA vision to create a national evaluation system for health technology.

**Olympus**, of Center Valley, Pa., will expand its Endotherapy product line, adding to its efforts in endoscopic submucosal dissection (ESD) with its 3-in-1 SB knives to enable mucosal incision, submucosal dissection and hemostasis for controlled, precision cutting to remove early gastrointestinal cancers that have not entered the muscle layer. The SB knives are a line of scissor-type ESD knives available in the U.S. through an exclusive distribution agreement between Olympus and Sumitomo Bakelite Co. Ltd. Olympus also will co-promote Eleview in the U.S. with Aries Pharmaceuticals. Eleview provides easy and safe resection with increased visibility of target lesion margins and less risk of perforation. Eleview was developed by Cosmo Pharmaceuticals NV Olympus and Aries, the U.S. distribution arm of Aries Ltd. and a wholly owned subsidiary of Cosmo, will work together to promote Eleview to end-user customers and will each sell the product through their existing distribution networks.

San Diego-based **Resmed Inc.**, developer of devices and cloud-based software applications that better diagnose, treat and manage sleep-disordered breathing, reported the Munich District Court decided that Resmed's Airsense 10, Aircurve 10, Lumis and their humidifiers do not infringe a **Fisher & Paykel** German utility model (a short-term patent), DE 20 2013 012 358 U1. Although Resmed's products do not infringe, Resmed will continue its challenge of the validity of the German utility model before the German Patent and Trademark Office. To date, no German court has found that Resmed's products infringe a Fisher & Paykel patent in any of the three cases brought by Auckland, New Zealand-based Fisher & Paykel against Resmed in Germany. By contrast, the same German court concluded in September that Fisher & Paykel's Simplus, Eson and Eson 2 masks infringe Resmed patents, while staying the proceedings pending the outcome of invalidation proceedings. Resmed is now defending its own patents in the European Patent Office.

# Neurology Extra

## Keeping you up to date on recent developments in neurology

*By Andrea Gonzalez, Production Editor*

### Key mechanism determined for transcranial stimulation

Researchers from HRL Laboratories LLC, of Malibu, Calif., have determined how noninvasive transcranial direct current stimulation (tDCS) could increase performance of associative learning. The researchers found that when applied to the prefrontal cortex, tDCS affects a wide portion of the brain, causing changes in functional connectivity between different brain areas that increased learning speed in macaques. This new understanding of what tDCS does to the brain and its confirmation of tDCS as a learning aid comes in the context of controversy over previous reports that seemed to show no effect on neuron firing rates in cadaver heads, which was generally believed to be the mechanism of interest. tDCS-based behavioral results have also been questioned on statistical and methodological grounds, but those analyses have been criticized. The new HRL study confirmed behavioral changes that sped up learning with tDCS and found that learning improved regardless of neuron firing rates. Done in collaboration with McGill University in Montreal and Soterix Medical in New York, the study was sponsored by the Defense Advanced Research Project Agency (DARPA)'s Restoring Active Memory (RAM) program. Published Oct. 12, 2017, in the journal *Current Biology*, tDCS in animals showed learning accelerated by about 40 percent when given 2 mA noninvasively to the prefrontal cortex without increased neuronal firing. This study showed it was modulated connectivity between brain areas, not neuron firing rates, that accounted for the increased learning speed. The behavioral task in this experiment was associative learning. Macaque monkeys had to learn arbitrary associations between a visual stimulus and a location where they would get a reward – a visual foraging task. The initial foraging trials took about 15 seconds, and once the animal learned the location of the reward, it took approximately two seconds to recall and find the target. Subjects in the control condition required an average of 22 trials to learn to obtain the reward right way. With tDCS they required an average of 12 trials. The study is titled "Transcranial direct current stimulation facilitates associative learning and alters functional connectivity in the primate brain."

### Better 'mini brains' could help scientists identify treatments for Zika-related brain damage

UCLA researchers, led by Ben Novitch, UCLA's Ethel Scheibel Professor of Neurobiology, have developed an improved technique for creating simplified human brain tissue from stem cells. Because these so-called "mini brain organoids" mimic human brains in how they grow and develop, they're vital to studying complex neurological diseases. In the study titled "Self-organized cerebral organoids with human-specific features predict effective drugs to combat Zika virus infection," published Oct. 10 in the journal *Cell Reports*, the researchers used the organoids to better understand how Zika infects and damages fetal brain tissue, which enabled them to identify drugs that could prevent the virus's damaging effects. For about five years, scientists have been using human pluripotent stem cells to develop mini brain organoids. But the organoids they produced have generally been difficult to use for research because they had highly variable structures and inconsistent cellular composition. The organoids developed by Novitch's group have a stratified structure that accurately mimics the human brain's onion-like layers, they survive longer and have a larger and more uniform shape. The researchers found critical similarities between the organoids they developed and real human brain tissue. Among them: The organoids' anatomy closely resembled that of the human cortex, the region of the brain associated with thought, speech and decision making; and a diverse array of neural cell types commonly found in the cortex were all present in the organoids, and they exhibited electrical activities and network function, meaning they were capable of communicating with one another much like the neural networks in the human brain do. The UCLA scientists also found that they could modify their methodology to make other parts of the brain including the basal ganglia, which are involved in the control of movement and are affected by neurodegenerative conditions such as Parkinson's disease and Huntington's disease. When the team exposed the organoids to Zika, they discovered specifically how the virus destroys neural stem cells, the cells from which the brain grows during fetal development. Novitch's team found that there are four specific molecules, called receptors, on the outer surface of neural stem cells; previous studies have indicated that the Zika virus could bind to these receptors and infect the cells. The researchers then mapped the changes that occur in the neural stem cells after Zika infection, presenting a clearer picture of how the virus infiltrates and harms fetal brain tissue. The researchers tested several drugs on the Zika-infected organoids. They found three that are effective at blocking the virus's entry into the brain tissue, including two that protected neural stem cells by preventing the interaction between the virus and entry receptors on the neural stem cells. The team plans to continue using its improved organoids to better understand human brain development and to learn more about autism spectrum disorders, epilepsy and other neurological conditions.

### Bright light therapy at midday helped patients with bipolar depression

Daily exposure to bright white light at midday significantly decreased symptoms of depression and increased functioning in people with bipolar disorder, a recent Northwestern Medicine study found. Previous studies found morning bright light therapy reduced symptoms of depression in patients

Continues on next page

# Neurology Extra

Continued from previous page

with seasonal affective disorder. But patients with bipolar disorder can experience side effects such as mania or mixed symptoms from this type of depression treatment. This new study implemented a midday light therapy intervention in an effort to provide relief for bipolar depression and avoid those side effects. The study included 46 participants who had at least moderate depression, bipolar disorder and who were on a mood stabilizer. Patients were randomly assigned to either a 7,000 lux bright white light or a 50 lux placebo light. The light therapy patients were instructed to place the light box about one foot from their face for 15-minute sessions to start. Every week, they increased their exposure to the light therapy by 15-minute increments until they reached a dose of 60 minutes per day or experienced a significant change in their mood. Compared to dim placebo light, study participants assigned to bright white light between noon and 2:30 p.m. for six weeks experienced a significantly higher remission rate (minimal depression and return to normal functioning). More than 68 percent of patients who received midday bright light achieved a normal level of mood, compared to 22.2 percent of patients who received the placebo light. The group receiving bright light therapy also had a much lower average depression score of 9.2 compared to 14.9 for the placebo group and significantly higher functioning, meaning they could go back to work or complete tasks around the house they hadn't been able to finish prior to treatment. The study, titled "Adjunctive bright light therapy for bipolar depression: a randomized double-blind placebo-controlled trial," was published Oct. 3, 2017, in the *American Journal of Psychiatry*. "Effective treatments for bipolar depression are very limited," said lead author Dorothy Sit, associate professor of psychiatry and behavioral sciences at Northwestern University Feinberg School of Medicine. "This gives us a new treatment option for bipolar patients that we know gets us a robust response within four to six weeks." Patients also experienced minimal side effects from the therapy. No one experienced mania or hypomania, a condition that includes a period of elation, euphoria, irritability, agitation, rapid speech, racing thoughts, a lack of focus and risk-taking behaviors.

### School year 'relative age' causing bias in ADHD diagnosis, says research

Younger primary school children are more likely to be diagnosed with attention deficit hyperactivity disorder (ADHD) than their older peers within the same school year, new research has shown. The study, led by a child psychiatrist at The University of Nottingham with researchers at the University of Turku in Finland, suggests that adults involved in raising concerns over a child's behavior – such as parents and teachers – may be misattributing signs of relative immaturity as symptoms of the disorder. In their research, published Oct. 9, 2017, in *The Lancet Psychiatry*, the experts used nationwide population data from all children in Finland born between 1991 and 2004 who were diagnosed with ADHD from the school starting age onwards. In Finland, children start school during the calendar year they turn 7 years of age, with the school year starting in mid-August. Therefore, the eldest in a school year are born in January (aged 7 years and 7 months) and the youngest in December (6 years and 7 months). The results showed that younger children were more likely to be diagnosed with ADHD than their older same-year peers – boys by 26 percent and girls by 31 percent. For children under the age of 10 years, this association got stronger over time – in the more recent years 2004-2011, children born in May to August were 37 percent more likely to be diagnosed and those born in September to December 64 percent, compared to the oldest children born in January to April. The study found that this "relative age affect" could not be explained by other behavioral or developmental disorders that may also have been affecting the children with an ADHD diagnosis. However, the experts warn, the study did have some important limitations – the data did not reveal whether any of the young children were held back a year for educational reasons and potentially misclassified as the oldest in their year group when in fact they were the youngest of their original peers. The flexibility in school starting date could explain why the rate of ADHD in December-born children (the relatively youngest) were slightly lower than those for children born in October and November. And while the records of publicly funded specialized services, which are free at the point of access, will capture most children who have received a diagnosis of ADHD, it will miss those who were diagnosed in private practice. Lead author Kapil Sayal, professor of child and adolescent psychiatry at the University of Nottingham's School of Medicine, said: "Parents and teachers as well as clinicians who are undertaking ADHD assessments should keep in mind the child's relative age. From an education perspective, there should be flexibility with an individualized approach to best meets the child's needs." The study is titled "Relative age within the school year and diagnosis of attention-deficit hyperactivity disorder: a nationwide population-based study."