BioWorld MedTech

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Miracor scores breakthrough device designation for PICSO

By Liz Hollis, Staff Writer

A little less than a year after it reported the final close of a series D financing, Miracor Medical SA, of Awans, Belgium, has been granted breakthrough device designation by the U.S. FDA for its Pressure-Controlled Intermittent Coronary Sinus Occlusion (PICSO) Impulse System for the treatment of ST-elevated myocardial infarction (STEMI) patients.

The system is intended to reduce infarct size after STEMI, which is strongly associated with reductions in heart failure hospitalizations and reduced mortality.

See Miracor, page 5

Inside

China slaps tariffs on more U.S. med-tech exports

By Elise Mak, Staff Writer

BEIJING – The trade war has escalated. On Aug. 23, China announced retaliatory tariffs on $75 billion of U.S. exports, 10 days after the U.S. slapped the same amount on $300 billion of Chinese goods. Once again, the med-tech sector is neck deep in this tariff tit-for-tat.

"The tariffs announced by China on Aug 23 cover over 50 kinds of medical devices," Xiaoqing Wang, a sales representative of China-based export consultancy firm ETCN, told *BioWorld MedTech*.

See Tariffs, page 6

Coopercompanies misses Q3 target, lowers outlook

By Meg Bryant, Staff Writer

The Coopercompanies Inc. reported mixed results for the fiscal 2019 third quarter, with total revenue of $679.4 million falling shy of its target of $687 million for the period. Sales in its Coopervision (CVI) business grew 6% to $509.1 million on a pro forma basis, compared with the same period a year ago, but were hurt by competition in multifocal contact lenses and some inventory destocking related to market jitters around Brexit. In Coopersurgical (CSI), soft sales of the Paragard

See Cooper, page 7

New process creates complex structures 10 times faster than 3D bioprinting

By Annette Boyle, Staff Writer

Researchers from the Swiss École Polytechnique Fédérale de Lausanne (EPFL) and the University Medical Center Utrecht in the Netherlands have developed a bioprinting process that allows simultaneous production of the entire volume of complex shapes, providing much greater flexibility and faster production than layer-by-layer 3D printing. Details on the process, called volumetric

See Bioprinting, page 8

Superbranche develops dendritic nanomaterials for early cancer diagnosis

By Bernard Banga, Staff Writer

PARIS – Startup Superbranche SAS, from Strasbourg, France, is developing a new generation of functionalized metallic oxide nanoparticles that are designed to facilitate early diagnosis of and targeted therapy for cancer.

"Our dendritic architectural approach to nanomaterials addresses issues of accuracy, early diagnosis and reduction of side effects

See Superbranche, page 9

Holiday notice

The offices of *BioWorld MedTech* were closed in observance of the Labor Day holiday in the U.S. No issue was published Monday, Sept. 2.

BioWorld MedTech's Cardiology Extra

Staff Writer Liz Hollis on one of med-tech's key sectors

Read this week's edition

Appointments and advancements

Woodland Hills, Calif.-based **Endonovo Therapeutics Inc.**, a commercial-stage developer of noninvasive electroceutical therapeutic devices, named orthopedic surgeon Geoffrey Abrams to its scientific advisory board.

Männedorf, Switzerland-based **Tecan Group Ltd.** said its board has appointed Tania Micki to succeed Rudolf Eugster as chief financial officer and a member of the management board. Eugster will be leaving the company following the annual financial statements 2019 and their presentation in March 2020. Micki will join the company by March 1, 2020, at the latest, to ensure an orderly transition. Tecan is a provider of laboratory instruments and solutions in biopharmaceuticals, forensics and clinical diagnostics.

Other news to note

Aterica Digital Health Corp., a Waterloo, Ontario-based developer of measurement, monitoring and diagnostic products, reported that its Veta Smart Case & App for epinephrine autoinjectors is now available in Walgreens pharmacies. The Veta Smart Case is currently compatible with Epipen, Epipen Jr and Mylan's authorized generics to Epipen autoinjectors.

GN Hearing Care Corp., a Bloomington, Minn.-based manufacturer of hearing aids and headphones, has launched a line of custom-crafted hearing aids that incorporate its new Resound Linx Quattro technology. Four options are available: the Completely-in-Canal (CIC) 2.4 GHz wireless hearing aid for direct streaming, high-quality In-the-Canal (ITC) and In-the-Ear (ITE) models and the Mic-in-Helix (MIH) hearing aid.

Minneapolis-based **Inspire Medical Systems Inc.**, a provider of solutions for obstructive sleep apnea, reported the publication of two more draft local coverage decisions (LCDs) covering its Inspire therapy. The Medicare administrative contractors (MAC) that issued the policies are Novitas Solutions and First Coast Service Options, which together represent 12 states and the District of Columbia. First Coast simultaneously cancelled its current negative policy on the device. The final LCD are anticipated in early 2020. Two other MACs, Noridian and Palmetto, previously issued draft coverage policies for the Inspire therapy.

Singapore-based **Syntellix Asia Pte. Ltd.**, the Asian subsidiary of Syntellix AG, an orthopedic implant company, and **Beijing Chunlizhengda Medical Instruments Co. Ltd.**, a manufacturer of orthopedic and trauma devices, reported a collaboration to introduce Syntellix's Magnezix magnesium alloy-based implants into China. The contract calls for a minimum purchase of more than €100 million (US$109.85 million) over five years. China's National Medical Products Administration has granted Syntellix an "innovative pathway" for Magnezix, which aims to speed marketing authorization.

Titan Medical Inc., a Toronto-based company developing a single-port robotic surgical system, has entered a common share purchase agreement with **Aspire Capital Fund LLC** whereby Aspire will purchase up to $35 million of Titan common shares at Titan's request, over a period lasting until Feb. 28, 2022. Under the agreement, Titan will immediately sell 1,777,325 common shares to Aspire at a per share price of $1.6879, for gross process of $3 million. On any business day, Titan can direct Aspire to buy up to 100,000 common shares valued up to but not exceeding $500,000.

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Send all press releases and related information to newsdesk@bioworldmedtech.com.

BioWorld MedTech stock report for public med-tech companies

Company	Symbol	Close 8/23	Close 8/30	Change Week	Change YTD	Vol (000)
Abbott Labs	ABT	81.93	85.32	4.14	17.96	19600
Abiomed	ABMD	189.59	193.07	1.84	-40.60	1987
Accelerate Dx	AXDX	17.77	18.79	5.74	63.39	782
Accuray	ARAY	2.61	2.68	2.68	-21.41	1587
Adaptive Biotech	ADPT	43.11	50.85	17.95	154.25	1439
Agilent Tech	A	69.55	71.11	2.24	5.41	9488
Align Tech	ALGN	175.04	183.11	4.61	-12.57	5308
Allergan	AGN	158.96	159.72	0.48	19.50	12772
Allied Healthcare	AHPI	1.45	1.4	-3.45	-23.50	5
Allscripts	MDRX	9.27	9.08	-2.05	-5.81	4623
Alphatec	ATEC	5.82	5.23	-10.14	128.38	2699
Angiodynamics	ANGO	18.32	18.37	0.27	-8.74	672
Anika Therapeutics	ANIK	55.91	56.76	1.52	68.88	610
Antares Pharma	ATRS	3.30	3.24	-1.82	19.12	4264
Apollo Endosurgery	APEN	3.55	3.54	-0.28	2.61	25
Apyx Medical	APYX	6.80	7.11	4.56	9.72	170
Atricure	ATRC	26.42	27.39	3.67	-10.49	1340
Atrion	ATRI	759.21	777.15	2.36	4.87	51
Avanos Medical	AVNS	32.75	33.18	1.31	-25.92	1241
Avedro	AVDR	21.17	23.42	10.63	67.29	1412
Axogen	AXGN	15.96	15.85	-0.69	-22.42	1590
Axonics	AXNX	33.14	33.27	0.39	120.19	664
Baxter Intl	BAX	85.03	87.95	3.43	33.62	10045
Becton Dickinson	BDX	248.31	253.92	2.26	12.69	3503
Biolife Solutions	BLFS	19.31	20.69	7.15	71.99	543
Bionano Genomics	BNGO	1.60	1.49	-6.88	-71.56	3304
Bio-Rad Labs	BIO	332.67	337.71	1.52	45.43	824
Bio-Techne	TECH	187.62	191.57	2.11	32.37	677
Biotelemetry	BEAT	40.64	39.65	-2.44	-33.61	1156
Boston Scientific	BSX	41.17	42.73	3.79	20.91	22627
Brainsway	BWAY	10.25	10	-2.44	-9.09	72
Bruker	BRKR	41.64	43.17	3.67	45.01	2863
Cantel Medical	CMD	86.15	91.93	6.71	23.48	935
Cardinal Health	CAH	42.79	43.13	0.79	-3.30	16039
Cardiovascular Sys	CSII	48.22	48.43	0.44	69.99	1218
Caredx	CDNA	22.80	22.82	0.09	-9.23	3543
Castle Biosci	CSTL	23.50	27.92	18.81	74.50	794
Celcuity	CELC	15.74	17.99	14.29	-25.01	56
Cellectar Biosci	CLRB	2.12	2.12	0.00	36.77	164
Cerus	CERS	5.28	5.37	1.70	5.92	3585
Check Cap	CHEK	1.99	2.02	1.51	-6.05	93
Chembio Dx	CEMI	4.89	5.05	3.27	-10.78	269
CHF Solutions	CHFS	2.54	2.57	1.18	-62.54	218
Conformis	CFMS	1.92	2.14	11.46	494.44	4659
Conmed	CNMD	99.29	100.77	1.49	56.96	707
Cooper Companies	COO	321.67	309.75	-3.71	21.71	1952
Corindus Vascular	CVRS	4.28	4.25	-0.70	405.95	7488
CRH Medical	CRHM	3.06	3.08	0.65	0.33	116
Cryolife	CRY	26.07	26.8	2.80	-5.57	964
Cutera	CUTR	29.95	28.87	-3.61	69.62	389
Cytosorbents	CTSO	4.51	4.46	-1.11	-44.80	653
Danaher	DHR	135.40	142.09	4.94	37.79	10232
Dariohealth	DRIO	0.36	0.4	11.11	-48.72	431
Daxor	DXR	8.88	8.98	1.13	9.51	7
Dentsply Intl	XRAY	51.67	52.13	0.89	40.10	5951
Dexcom	DXCM	173.55	171.61	-1.12	43.25	4161
Digirad	DRAD	4.41	4.5	2.04	-21.05	13
Dynatronics	DYNT	1.23	1.27	3.25	-53.48	6
Edap Tms	EDAP	3.25	3.17	-2.46	71.35	880
Edwards Lifesci	EW	212.04	221.84	4.62	44.83	3295
Ekso Bionics	EKSO	0.76	0.66	-13.16	-46.77	2969
Electrocore	ECOR	1.57	1.91	21.66	-69.49	485
Electromed	ELMD	5.20	5.73	10.19	12.57	89
Endologix	ELGX	5.50	5.36	-2.55	-25.56	1578
Enzo Biochem	ENZ	3.01	3.25	7.97	16.91	471

Company	Symbol	Close 8/23	Close 8/30	Change Week	Change YTD	Vol (000)
Establishment Labs	ESTA	20.48	19.88	-2.93	-27.50	311
Evolus	EOLS	14.96	17.24	15.24	44.87	1782
Fluidigm	FLDM	5.56	5.58	0.36	-35.27	5661
Fonar	FONR	24.28	24.1	-0.74	19.07	119
Fresenius Medical	FMS	33.41	33.6	0.57	3.74	975
Gamida Cell	GMDA	3.90	3.7	-5.13	-62.78	106
Genfit	GNFT	16.69	17.3	3.65	-14.86	148
Genmark Dx	GNMK	6.11	5.99	-1.96	23.25	1041
Genomic Health	GHDX	73.26	76.66	4.64	19.02	1743
Glaukos	GKOS	58.58	64.31	9.78	14.49	3759
Globus Medical	GMED	50.31	51.07	1.51	18.00	3369
Grifols	GRFS	21.42	21.3	-0.56	16.01	6893
Guardant Health	GH	94.64	87.53	-7.51	132.85	5653
Guardion Health	GHSI	0.25	0.25	0.00	-93.75	17879
Haemonetics	HAE	130.15	133.53	2.60	33.46	1751
Health Catalyst	HCAT	38.63	39.86	3.18	53.31	1329
Henry Schein	HSIC	59.46	61.62	3.63	-21.52	5439
Hill-Rom	HRC	104.30	107.68	3.24	21.60	1393
Hologic	HOLX	48.13	49.37	2.58	20.12	9583
HTG Molecular Dx	HTGM	0.94	0.93	-1.06	-63.39	689
Icad	ICAD	5.98	6	0.33	62.16	314
ICU Medical	ICUI	161.66	161.75	0.06	-29.56	970
Ideaya Biosci	IDYA	6.36	6.8	6.92	-32.00	49
Illumina	ILMN	279.44	281.34	0.68	-6.20	3337
Inogen	INGN	44.60	46.37	3.97	-62.66	2020
Inovio Pharma	INO	2.18	2.16	-0.92	-46.00	2679
Inspire	INSP	64.02	69.51	8.58	64.52	1298
Insulet	PODD	154.09	154.17	0.05	94.36	2495
Integer	ITGR	72.59	72.4	-0.26	-5.06	836
Integra Lifesci	IART	59.90	60.02	0.20	33.08	2942
Interpace Dx	IDXG	0.75	0.74	-1.33	-7.50	523
Intersect ENT	XENT	15.37	16.38	6.57	-41.87	1482
Intricon	IIN	17.45	17.4	-0.29	-34.04	461
Intuitive Surgical	ISRG	484.58	511.34	5.52	6.77	2646
Invacare	IVC	5.02	4.84	-3.59	12.56	1463
Invitae	NVTA	24.00	24.26	1.08	119.35	8719
Invivo Therapeut	NVIV	0.57	0.61	7.02	-59.60	163
Iradimed	IRMD	19.14	19.18	0.21	-21.59	245
Irhythm	IRTC	68.59	76.12	10.98	9.56	1252
Iridex	IRIX	2.50	2.5	0.00	-46.81	223
Itamar Medical	ITMR	9.25	9.29	0.43	-18.51	4
Labcorp	LH	165.86	167.56	1.02	32.61	2573
Lantheus Holdings	LNTH	21.93	21.76	-0.78	39.04	1110
Lemaitre Vascular	LMAT	31.05	31.66	1.96	33.93	264
Lianluo Smart	LLIT	0.83	0.77	-7.23	-31.86	19
Livanova	LIVN	75.47	77.63	2.86	-15.13	1444
Livongo Health	LVGO	34.64	30.64	-11.55	9.43	4419
Luminex	LMNX	19.79	20.5	3.59	-11.29	694
Masimo	MASI	146.55	153.25	4.57	42.73	1180
Medigus	MDGS	1.91	2.04	6.81	-21.54	34
Medtronic	MDT	106.05	107.89	1.74	18.61	19164
Meridian Biosci	VIVO	9.23	9.23	0.00	-46.83	828
Merit Medical Sys	MMSI	34.23	34.78	1.61	-37.68	2465
Mesa Labs	MLAB	206.69	221.23	7.03	6.16	406
Microbot Medical	MBOT	4.95	5.37	8.48	212.21	233
Micron Solutions	MICR	2.35	2.4	2.13	-9.77	2627
Misonix	MSON	20.01	19.58	-2.15	22.30	156
Motus GI	MOTS	2.69	2.64	-1.86	-15.11	228
Myomo	MYO	0.81	0.79	-2.47	-45.14	465
Nanostring Tech	NSTG	23.35	25.48	9.12	71.81	2926
Natera	NTRA	32.32	32.95	1.95	136.03	2527
Natus Medical	NTUS	28.83	27.68	-3.99	-18.66	744
Neuronetics	STIM	9.47	10.67	12.67	-44.86	272
Nevro	NVRO	82.42	83.73	1.59	115.30	1815
Novocure	NVCR	92.49	90.86	-1.76	171.39	3920

Continues on next page

BioWorld MedTech stock report for public med-tech companies

Continued from previous page

Company	Symbol	Close 8/23	Close 8/30	Change Week	Change YTD	Vol (000)
Nuvasive	NUVA	63.44	63.52	0.13	28.17	2011
Nuvectra	NVTR	1.32	1.95	47.73	-88.07	17134
Obalon Therapeutics	OBLN	2.21	2.05	-7.24	-90.10	2363
Oncocyte	OCX	1.86	1.98	6.45	43.48	512
Opko Health	OPK	1.83	1.84	0.55	-38.87	13731
Optinose	OPTN	6.07	7.66	26.19	23.55	1560
Orasure Tech	OSUR	6.80	6.6	-2.94	-43.49	1668
Orthofix Intl	OFIX	51.37	50.84	-1.03	-3.14	316
Orthopediatrics	KIDS	30.67	32.19	4.96	-7.71	283
Oxford Immunotec	OXFD	13.49	13.36	-0.96	4.54	662
Pacific Biosci	PACB	5.61	5.55	-1.07	-25.00	5118
Pavmed	PAVM	1.01	0.98	-2.97	2.08	662
Penumbra	PEN	139.74	145.55	4.16	19.11	1560
Perkinelmer	PKI	80.76	82.7	2.40	5.28	3111
Personalis	PSNL	18.86	19.35	2.60	13.82	976
Predictive Oncology	POAI	0.58	0.55	-5.17	-9.84	144
Pro-Dex	PDEX	14.09	14.34	1.77	18.71	65
Pulse Biosci	PLSE	11.25	11.99	6.58	4.62	115
Quest Dx	DGX	101.60	102.37	0.76	22.94	4962
Quidel	QDEL	58.34	62.9	7.82	28.84	1479
Quotient	QTNT	9.25	9.02	-2.49	47.39	1387
Ra Medical Sys	RMED	1.87	1.54	-17.65	-80.63	249
Radnet	RDNT	14.47	13.91	-3.87	36.77	947
Resmed	RMD	132.18	139.3	5.39	22.33	2097
Restoration Robotics	HAIR	0.66	0.6	-9.09	36.36	1051
Retractable Tech	RVP	0.79	0.8	1.27	33.33	120
Royal Philips	PHG	45.91	47.08	2.55	34.09	2001
RTI Surgical	RTIX	3.05	3.18	4.26	-14.05	490
Seaspine	SPNE	10.51	10.99	4.57	-39.75	192
Second Sight	EYES	0.76	0.78	2.63	-12.36	710
Senseonics	SENS	1.05	1.02	-2.86	-60.62	10560
Sensus Healthcare	SRTS	6.13	6.42	4.73	-13.36	62
Shockwave Medical	SWAV	39.60	41.85	5.68	146.18	1300
SI-Bone	SIBN	18.85	19.44	3.13	-6.94	602
Sientra	SIEN	6.58	6.83	3.80	-46.26	3229
Silk Road	SILK	41.13	43.09	4.77	115.45	840
Smith & Nephew	SNN	47.01	47.96	2.02	28.30	2497
Soliton	SOLY	12.85	11.96	-6.93	139.20	1315
Staar Surgical	STAA	29.71	30.11	1.35	-5.64	1104
Steris	STE	148.46	154.4	4.00	44.50	2252
Strata Skin Sci	SSKN	1.75	1.9	8.57	-26.92	634
Stryker	SYK	214.10	220.66	3.06	40.77	3957
Surmodics	SRDX	42.68	47.06	10.26	-0.42	368
T2 Biosystems	TTOO	1.19	1.33	11.76	-55.81	5795
Tactile Sys	TCMD	48.40	50.44	4.21	10.74	454
Tandem Diabetes	TNDM	66.81	72.43	8.41	90.76	7000
Teladoc	TDOC	56.05	57.88	3.26	16.76	3587
Teleflex	TFX	357.94	363.92	1.67	40.79	1182
Thermo Fisher Sci	TMO	269.36	287.06	6.57	28.27	7322
Transenterix	TRXC	0.97	0.92	-5.15	-59.29	7216
Transmedics	TMDX	23.28	23.95	2.88	49.69	353
Trinity Biotech	TRIB	1.45	1.36	-6.21	-40.61	414
Twist Biosci	TWST	28.07	29.03	3.42	25.73	824
Utah Medical	UTMD	89.70	98.32	9.61	18.34	45
Vapotherm	VAPO	12.83	11.6	-9.59	-41.85	859
Varian Medical Sys	VAR	106.12	105.93	-0.18	-6.51	3757
Veracyte	VCYT	24.66	26.5	7.46	110.65	1923
Vericel	VCEL	16.25	16.54	1.78	-4.94	1994
Viewray	VRAY	3.91	3.94	0.77	-35.09	5463
Vocera Comm	VCRA	23.50	22.95	-2.34	-41.68	1767
Volitionrx	VNRX	4.01	3.61	-9.98	99.45	231
West Pharma	WST	143.33	145.46	1.49	48.38	946
Wright Medical	WMGI	21.84	20.85	-4.53	-23.40	6845
Xtant Medical	XTNT	2.81	2.55	-9.25	58.39	24
Zimmer Biomet	ZBH	133.64	139.2	4.16	34.21	4340

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: +2.13%
Range: -**17.65**% to +**47.73**%; Number of companies: 195 (not market weighted)

Average percent change year-to-date: +15.98%
Range: -**93.75**% to +**494.44**%; Number of companies: 195 (not market weighted)

10 biggest U.S. gainers for the week

Share price by percent		Share price by dollars	
Optinose	26.19	Intuitive Surgical	26.76
Castle Biosci	18.81	Atrion	17.94
Adaptive Biotech	17.95	Thermo Fisher Sci	17.70
Evolus	15.24	Mesa Labs	14.54
Celcuity	14.29	Edwards Lifesci	9.80
Neuronetics	12.67	Utah Medical	8.62
Conformis	11.46	Align Tech	8.07
Irhythm	10.98	Adaptive Biotech	7.74
Avedro	10.63	Irhythm	7.53
Surmodics	10.26	Resmed	7.12

10 biggest U.S. losers for the week

Share price by percent		Share price by dollars	
Livongo Health	-11.55	Cooper Companies	-11.92
Alphatec	-10.14	Guardant Health	-7.11
Volitionrx	-9.98	Livongo Health	-4.00
Vapotherm	-9.59	Dexcom	-1.94
Xtant Medical	-9.25	Novocure	-1.63
Guardant Health	-7.51	Vapotherm	-1.23
Obalon Therapeutic	-7.24	Natus Medical	-1.15
Soliton	-6.93	Cutera	-1.08
Gamida Cell	-5.13	Biotelemetry	-0.99
Wright Medical	-4.53	Wright Medical	-0.99

Miracor

Continued from page 1

"Despite effective treatment, patients with STEMI often have large heart attacks, resulting in heart failure. Early studies have shown the potential for PICSO to reduce infarct size in STEMI." Gregg Stone explained. Stone serves as professor of medicine at the Columbia University Medical Center, director of cardiovascular research and education at the Center for Interventional Vascular Therapy at New York-Presbyterian Hospital, and co-director of medical research and education at the Cardiovascular Research Foundation in New York.

Last year's investors appeared to see the potential for the product. The round was led by China-based investor Ming Capital and an undisclosed strategic investor. The cash infusion brought the total raised by the company to about $72 million since its inception in 2008. The final close of the series D round was €30 million (US$33.2 million). (See *BioWorld MedTech*, Sept. 5, 2018.)

The investment was earmarked for clinical testing and preparation for commercialization of the system, which consists of a balloon-tipped catheter and a driving console. Its impulse catheter is inserted via the femoral vein and placed in the coronary sinus using a steerable guide sheath. Intermittent coronary sinus occlusion is controlled by an impulse console using the Wien Algorithm, which continuously monitors coronary sinus pressure dynamics and automatically sets the time of occlusion and release phases.

PICSO therapy is applied after flow restoration and during coronary artery stenting in patients presenting with acute myocardial infarction. It is automatically adapted to the patient's anatomy and hemodynamics and extends average cath lab time by only 20 to 30 minutes.

"The PICSO Impulse System represents a novel technology that has taken the principles from a surgical practice (retroperfusion and intermittent coronary sinus occlusion), and translated [them] into a percutaneous therapy that can be used to perfuse ischemic myocardium," Olivier Delporte, CEO of Miracor, told *BioWorld MedTech* when asked what differentiated his product.

"The novel mechanism of action of the PICSO Impulse System addresses the limitations of the current primary [percutaneous coronary intervention] PCI approach, reducing both ischemia and reperfusion injury. The PICSO induced reduction of ischemic injury by re-distributing blood flow and the reduction of reperfusion injury by plasma skimming-induced clearance of microvascular obstruction addresses an unmet need to further reduce infarct size, thus positively influencing long-term cardiac function in STEMI patients."

Delporte added that the company is in discussions with the U.S. FDA for an IDE pivotal study. "We intend to submit and seek approval for the study in 2020."

The company also has made progress in Europe, with the PICSO-AMI-I study (NCT03625869) seeing the initiation of enrollment in July. Five patients already have been enrolled and randomized. "There are currently two sites open, and we look forward to enrollment accelerating with more sites open. We currently plan to open three to four more sites in the U.K.

> *"The novel mechanism of action of the PICSO Impulse System addresses the limitations of the current primary [percutaneous coronary intervention] PCI approach, reducing both ischemia and reperfusion injury.*
>
> Olivier Delporte
> CEO, Miracor Medical SA

over the next two months."

The prospective, multicenter, randomized, controlled PICSO-AMI-I study is expected to enroll 144 participants. The study is designed to prove superiority of PICSO used as an adjunct to PCI vs. PCI alone in reducing infarct size, as measured by cardiovascular magnetic resonance at five days.

Secondary efficacy endpoints include microvascular obstruction and cardiac function at five days and six months. Secondary clinical endpoints include death, heart failure-related hospitalization, new onset or worsening of heart failure. Endpoints will be followed up annually for three years.

Delporte noted that the company is focusing on obtaining the CE mark for it next-generation system, expected in early 2020. "With the CE mark, we plan on very selective usage over [the second half of] 2020 and [first half of] 2021, and that usage will be specific to some accounts rather to some countries," he replied when asked about launch plans. "We plan a broader launch as of mid-2021." ♦

Daily M&A

Constellation **Alpha Capital Corp.**, of West Palm Beach, Fla., a publicly traded special purpose acquisition company, and La Jolla, Calif.-based **Dermtech Operations Inc.**, which focuses on precision dermatology enabled by a non-invasive skin genomics platform, completed their business combination, first unveiled in May. Constellation has changed its name to Dermtech Inc. and effected a one-for-two reverse stock split of its common stock. As of Aug. 30, Constellation's common stock and warrants will continue trading on the Nasdaq Capital Market under the ticker symbols DMTK and DMTKW, respectively. Constellation's business combination with Dermtech was funded through a combination of Constellation shares, proceeds received from a private sale of Constellation stock at a split-adjusted price of $6.50 per common share, and cash remaining in Constellation's trust account after giving effect to stockholder redemptions. Immediately following the completion of the business combination, all of Constellation's officers and directors resigned. Dermtech's senior management has been appointed to serve in their current roles at the company, and all of the members of Dermtech's board will remain. John Dobak, CEO of Dermtech, will serve as CEO, and Matthew Posard, chairman of Dermtech's board, will serve as chair. In addition, Enrico Picozza, of Hlm Venture Partners, has been appointed as a director of the company's board.

Tariffs

Continued from page 1

"We've been receiving queries from clients about the latest tariffs."

The Customs Tariff Commission of China's State Council announced that 5% and 10% tariffs will be imposed on 5,078 U.S. goods in two batches, starting from Sept. 1 and Dec. 15, respectively.

Facing an almost immediate 5% tariff are disposables, including dermal fillers, blood type reagents, X-ray contrast agents, diagnostic reagents, dental cements and dental fillers, bone cements, sterile surgical gut and sterile absorbent hemostatic materials. Tariffs will start Sept. 1.

More medical devices will be subject to tariffs from Dec. 15.

Patient monitors, hearing screening and diagnostic devices, endoscopes and X-ray image intensifiers will face 10% tariffs.

The list for 5% tariff is much longer. It includes electrocardiographs, B type and color ultrasonic diagnostic apparatus, electrical diagnostic devices, diathermy equipment, blood transfusion equipment, respiratory equipment, light bulbs for medical and R&D use, medical vehicles, ultrasonic scanning devices, nuclear magnetic resonance imaging devices, audiometers, instruments and apparatus for ophthalmology, stethoscope, renal dialysis equipment, anesthesia equipment, intrauterine devices and orthopedic instruments.

Dental devices also take up a portion of the list. They include instruments for dental use, dental chairs, dentures, and dental X-ray application equipment.

China able to take up the slack?

Grace Fu Palma, CEO of Boston-based med-tech consulting firm China Med Device, told *BioWorld MedTech* that for disposables subject to 5% tariffs, China already has manufacturing capability domestically.

"The 10% tariff is to be applied for high value-added imaging and diagnostic equipment.," Palma said. "After tariffs on MRI, ECG, X-ray machines, B-san, color ultrasound and hemodialysis machines imposed last year, the Chinese government wants to further decrease reliance from high-tech innovation overseas."

In some ways, the pain of the trade war with the U.S. could help China find some gains in domestic production of devices and the potential reduction in the country's reliance on med-tech imports.

China has traditionally relied on imports for its high-end devices. To reduce this reliance, it has been pursuing a "Made in China 2025" strategic plan to make the country a dominant global force in high-tech manufacturing by increasing the quantity and quality of domestically produced goods.

The plan is at the very heart of why Washington declared a trade war on China and imposed tariffs of forcing transfers of intellectual property to achieve its goal.

This is not the first time that tariffs have been placed on medical devices. Only this time the scale is much higher. Last year, China put 28 medical devices on its tariff list for U.S. imports. Like this time, many of those were diagnostic imaging devices, including magnetic resonance imaging equipment, X-ray equipment and tubes, ophthalmology instruments and equipment, ultrasound equipment and computed tomography equipment.

The impact of the new tariffs is likely to hit U.S. diagnostic imaging companies most, said Karen Simpkins, a medical device market analyst at market intelligence provider Fitch Solutions, in a report. "While the U.S. maintains an overall trade deficit with China in medical devices of [about] $1.3 billion, it has a surplus for diagnostic imaging, which amounted to $218.8 million in 2017," she said.

China, on the other hand, seems to be safe from the trade war on the med-tech front, Stephen Sunderland, a partner at L.E.K. Consulting, told *BioWorld MedTech*.

"There should be few problems in finding local substitutes in China," he said, echoing Palma's view that China already has capability to manufacture some of the items on the list.

U.S. hitting back

China is not the only side imposing tariffs on medical devices. In April 2018, the Office of the U.S. Trade Representative (USTR) proposed an additional 25% tariff on Chinese goods worth around US$50 billion, including about 50 medical devices that ranged from consumables, diagnostic imaging, and dental products to orthopedics and prosthetics, patient aids and diagnostic reagents.

The Advanced Medical Technology Association (AdvaMed), for one, is engaging with the USTR on the trade talks, Ralph Ives, executive vice president of global strategy and analysis at AdvaMed, told *BioWorld MedTech*.

"AdvaMed strongly opposes tariffs by both sides on medical technology products that help save and improve millions of lives every day."

While the tariffs are worrying industry insiders, there are ways for U.S med-tech manufacturers to go around them to avoid putting patients at risk. Palma has come up with at least two possible solutions.

First is that they can consider contract manufacturing. She said the market authorization holder system is implemented in 21 provinces including the booming med-tech markets of Beijing, Shanghai, Guangdong, Jiangsu and Zhejiang. "The registration holders can now be independent of the manufacturers, encouraging foreign innovations to access China more swiftly and then to set up manufacturing facilities in China," Palma explained.

Second is re-exportation.

"U.S manufacturers may consider exporting to other countries such as Vietnam, the Philippines and Thailand before entering China to avoid the tariffs," she said.

Palma said some U.S. players have already begun to take this approach. Medtronic plc, for example, had its surgical power system approved in China through the marketing authorization holder system in Shanghai last April.

"Also, China is willing to absorb the extra cost on necessary high-tech devices. The impact on U.S companies would be less than expected," she said. ♦

Cooper

Continued from page 1

intrauterine device (IUD) helped hold down year-over-year growth to just 2%, to $170.3 million.

Within CVI, single-use sphere lenses were a strong performer, growing 9% to $146.3 million on a pro forma basis, driven by momentum from Clariti and Myday, which grew 23%. The segment comprised 29% of CVI revenue overall for the quarter. Toric lens revenue increased 8% to $163.1 million, while non-single-use sphere lenses inched up 2% to $147.3 million. Multifocals fell by 2% to $52.4 million.

> *"The faster we can ramp up production, the faster we'll get our multifocal out there.*
>
> Alan White
> President and CEO, Coopercompanies Inc.

"EMEA was a little softer than we were expecting, largely due to lower stocking levels, as that region experienced fluctuations working through challenges associated with Brexit," Albert White, president and CEO of Coopercompanies, told a third-quarter earnings call.

Multifocals competition

On multifocals, White blamed steep competition for the poor third-quarter results. "Some of our competitors have put up some pretty good lenses recently," he said. "We have a significant market share in the multifocal space … but there is some heightened competition there."

The Pleasanton, Calif.-based company is hoping introduction of its Myday multifocal will help to boost competition in the segment but does not have a clear timeline for that event due to issues around capacity. The company is bringing on production lines and will continue to do so in 2020, White said. "The faster we can ramp up production, the faster we'll get our multifocal out there."

Coopercompanies is also banking on future growth from its Misight lens for myopia. White said he's "keeping my fingers crossed" for FDA approval before the end of the calendar year, adding that there could be incremental investments in the product depending on the timing of FDA approval and accelerating demand outside the U.S. Prelaunch activities are already ramping up, he said.

Genetics stabilizing

In CSI, office and surgical products accounted for 62% of revenue for the quarter, up 2% year over year to $106.3 million. Fertility revenue was $64 million, down 4% year over year but up 5% pro forma. The company is seeing stability in its genomics business following a restructuring that reduced the number of laboratories from 16 to 3 and expects to see increased efficiencies going forward. White predicted continued mid to upper single digit long-term growth potential for the fertility sector.

He attributed "unexpectedly flat" sales of Paragard, which Coopercompanies acquired from Teva Pharmaceuticals in November 2017, to reduced promotional activities, including TV ads, and some inventory contraction at the physician level. "We found a clear correlation between our consumer awareness campaigns and unit growth, so our challenge moving forward is to optimize the return on this activity," he said.

The company expects Paragard to grow in the mid-single digits over the next several years, aided by 3% annualized unit growth and 3% coming from price. The company hasn't adjusted the price since it acquired the IUD, while some of its competitors have raised their base price on the hormonal side. With Paragard price up to 15% below some competitors, the company is considering a price hike. "There's certainly some room for us to take a decent increase in price and still be priced below them as one more tool in the toolbox in order to be able to sell the product, in addition to the fact that it's the only nonhormonal product in the market."

Narrowed guidance

Based on the FQ3 results, Coopercompanies said it expects full-year revenue of between $2,635-$2,655 million and pro forma growth of 6%-7%. The revised guidance is about $5 million less at midpoint than the prior forecast.

Wells Fargo Securities called the top-line miss and narrowed guidance disappointing, but noted the company was able to beat on the bottom line, thanks to a lower tax rate. "For FY20, COO continues to target low-double digit ex-FX operating income growth," analysts wrote in a research note. "When combined with a lower interest expense and higher tax rate, we see EPS growth in the mid- to high-single digit range for next year. Finally, management sounded confident that Misight U.S. approval could come by the end of CY19, which we would view as an important strategic positive despite any negative short-term impact on the P&L." ♦

Daily M&A

Sony Corp., of Tokyo, has tendered all of the common shares of **Olympus Corp.**, also of Tokyo, held by Sony back to Olympus. The transfer value was ¥80 billion (US$ 752.8 million). Sony and Olympus entered a business and a capital alliance agreement in 2012, aiming to collaborate in the medical and camera business areas. The following year, the two companies established a medical business joint venture company, Sony Olympus Medical Solutions Inc. (SOMED). Sony said it is determined to continue to focus on the medical business from a long-term perspective. It added that it will continue to have a relationship with Olympus, including operating SOMED, regardless of its sale of the shares.

Bioprinting

Continued from page 1

printing, and printer were published in *Advanced Materials*.

Three of the researchers have formed a new company, Readily3D SAS, to take the process to market.

Using visible light projection, the approach creates cell-laden tissues from gelatin-based photoresponsive hydrogels. The 3D accumulation of light inside the volumetric 3D printer causes solidification of the shape in seconds.

"Unlike conventional bioprinting – a slow, layer-by-layer process – our technique is fast and offers greater design freedom without jeopardizing the cells' viability," said co-author Damien Loterie, a researcher at the laboratory of applied photonics devices at EPFL. The speed of the process reduces the stress on the embedded cells, resulting in viability rates greater than 85%.

Real change coming to 3D printing

So far, the researchers have created a meniscus, a working valve similar to a heart valve, and a challenging part of a femur. The process permits production of interlocking structures and free-form shapes as well.

> *"This is just the beginning. We believe that our method is inherently scalable towards mass fabrication and could be used to produce a wide range of cellular tissue models, not to mention medical devices and personalized implants.*
>
> Christophe Moser
> Co-founder and business advisor, Readily3D SAS

"The characteristics of human tissue depend to a large extent on a highly sophisticated extracellular structure, and the ability to replicate this complexity could lead to a number of real clinical applications," said co-author Paul Delrot, a researcher at the laboratory of applied photonics devices at EPFL.

"We have currently printed one cm^3 to two cm^3 structures with cells," co-author Riccardo Levato, assistant professor at the regenerative medicine center and department of orthopedics, University Medical Center Utrecht told *BioWorld MedTech*. "The volume could, in theory, scale up to approximately one liter, and the resolution is below 100 um at the moment and improving continuously."

After printing, the researchers vascularized the constructs with endothelial cells. "The endothelial cells were seeded together with supporting pericyte-like cells into the pores of the trabecular bone model, which was laden with bioprinted osteogenic mesenchymal stromal cells (MSC). We used a standard endothelial culture media, and observed

spontaneous capillary formation. The presence of the bioprinted MSC provided signals that lead to better neo-vascularization, compared to controls in which printed MSCs were not present."

Fast production of constructs of clinically useful size could dramatically simplify testing of drugs in vitro, eliminating the need for animal testing, according to the team.

The technique produces a usable, customized hearing aid in 20 seconds.

"This is just the beginning. We believe that our method is inherently scalable towards mass fabrication and could be used to produce a wide range of cellular tissue models, not to mention medical devices and personalized implants," said Christophe Moser, head of the laboratory of applied photonics devices at EPFL.

From research to market

The team aims to bring their technique to market quickly. Readily3D should be up and running in a few months, Levato said. Patents are pending for the technology and the company has already received initial funding.

The company's current leadership includes three researchers involved in the recently published study –Loterie, who will be CEO; Delrot, chief technology officer; and Moser, business advisor. The basis of the company combined research Loterie did as a PhD student on the use of light shaping in complex media and Delrot's graduate research in additive manufacturing.

In addition to overseeing the work in the lab where the new printing process was developed, Moser has strong credentials in startups. He co-founded Composyt Light labs, which Intel acquired in 2014. He also co-founded and served as CEO of Ondax, which was acquired by Coherent Inc. last year.

"The bioprinting process will be commercialized soon for use in research labs," said Levato. "When it comes to biomedical applications, especially regenerative medicine, there is still work to do particularly regarding further biological and regulatory challenges, typical of engineered tissues, that still need to be considered. These include maturation of the printed constructs and their assessment of safety and functionality according to the guidelines provided by regulatory agency for advanced medical product." ♦

Superbranche

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from cancer treatment," Delphine Felder-Flesch, CEO of Superbranche, told *BioWorld MedTech*.

Current limits of nanoparticles used in oncology

Nanomedicine uses nanoparticles to better target tumor cells and limit side effects from chemotherapy. However, two major difficulties still need to be overcome: controlling the particle size so that they can be injected intravenously, and their "vectorization." This is the ability to graft molecules of biological value that will enable nanoparticles to penetrate the target cells accurately. To overcome these two pitfalls, two Strasbourg researchers, Delphine Felder-Flesch, research director at the Institute of Physics and Materials Science (IPCMS), and Sylvie Begin-Colin, director of the European School of Chemistry, Polymers and Materials (EPCM) propose using dendritic and magnetic nanoparticles.

Developed in 1987, dendrimers are synthetically produced monodisperse polymeric nanostructures with a highly branched tree-like architecture. Dendritic nanomaterials exhibit cooperativity properties that imply intensified signaling and targeting abilities. "Their method of synthesis allows for very precise control of their size, smaller than 10 nm, and an adaptability in accordance with the intended indication," said Felder-Flesch.

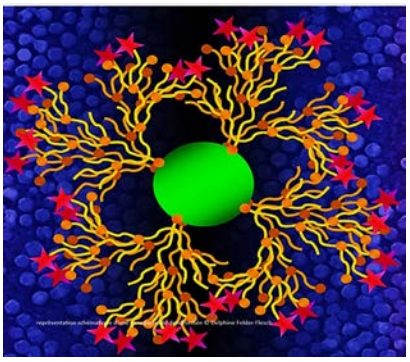
A spin-off from the IPCM, Superbranche was formed in May 2019 after 10 years of R&D on hybrid nanomaterials used in the diagnosis and treatment of cancer. The Alsace Region, the Cancéropole Grand Est, the University of Strasbourg, as well as the French National Agency for Research (ANR), the National Center for Scientific Research (CNRS) and the National Cancer Institute (INCA) and also the European Union, through its 2020 program, have invested $7 million in this new generation of nanomaterials.

Superbranche's technology is protected by three patents, belonging to the CNRS, the University of Strasbourg, the University Claude Bernard Lyon 1 and the Hospices Civils de Lyon. An exclusive license to use the patent for the manufacturing process and the applications for dendronized metallic oxide nanoparticles is currently being negotiated between Superbranche and CNRS Innovation. "We filed an option on the other two patents for radiopharmaceutical dendrimers. Exclusive operating licenses for these will also be requested in the coming months," said Felder-Flesch.

A scalable platform for theranostic nanomaterials

The new generation of Superbranche nanomaterials is based on a hybrid platform consisting of a metal oxide core coated with a thin, organic dendritic layer designed to stabilize the nanomaterial and make its intravenous injection possible. "The chemical design of the coating but also the versatility of the size and shape of the magnetic core give rise to nanomaterials optimized for both diagnosis and therapy. They are theranostic nanomaterials," said Felder-Flesch.

Validating the Superbranche dendronized nanoparticles technology was carried out through four preclinical feasibility studies in small animals, in partnership with various French, Belgian and Canadian hospitals. The first three feasibility studies have highlighted the properties of bio-distribution, bio-elimination and stealth (non-capture by the immune system) in these nano devices. The fourth study was devoted to in vitro cytotoxicity, the ability of these objects to provide a powerful MRI signal, regardless of the applied magnetic field, and to validate active targeting by confocal optical microscopy dealing with melanoma.



Dendritic structures allow intravenous injection of nanomaterials with special diagnostic and therapeutic properties. Credit: Superbranche

A market worth $95B

"The diagnosis and treatment of any solid tumor and the early diagnosis of the spread of solid cancers are the elective indications for our dendronized nanoparticles," said Felder-Flesch. The company is already marketing a dozen research use only (RUO) products to nanomedicine laboratories in both public and industrial research. Superbranche is positioning itself as a specialized producer of synthesized nanomaterials for nanomedicine – a market the company estimated is worth $95 billion with a compound annual growth rate (CAGR) of 12% between 2017 and 2023. In Europe, Superbranche is in direct competition with Nanobiotix SA and Nhtheraguix from France and Magforce AG from Germany.

Superbranche is distinguished from its competitors through its nanoplatform, adaptable to different indications. "Unlike other companies, we do not have just one product, but our skills as materials chemists allow us to adapt the material to suit every indication, whether for diagnosis or treatment. Then, the simplicity of our approach in developing nano-objects allows for intravenous injection," said Felder-Flesch.

A future opening of the capital

Superbranche, located in the IPCMS institute at Strasbourg University, has been winning prizes and awards. This summer, it was one of the 10 French startups to receive the grand jury prize at the iLab 2019 national competition for Deep Tech innovation.

The company has also just obtained a Deeptech grant from the public investment bank (BPI France) to carry out its RUO production project. "We plan to invite, from the end of this year, various offers for funding to scale up production for the sale of the first RUO products," said Felder-Flesch.

The company is preparing to raise $550,000 in early 2020 to complete funding for the R&D project already 60% funded by the iLab 2019 competition. "This will enable us to start, by the end of the Ilab project, a human clinical trial on our first diagnostic and therapeutic dendronized nanoparticle," said Felder-Flesch. ♦

Cardiology Extra

Keeping you up to date on recent developments in cardiology

By Liz Hollis, Staff Writer

Stretchable wireless sensor could monitor cerebral aneurysms

Researchers have disclosed that a wireless sensor could help clinicians evaluate the healing of aneurysms. The stretchable, battery-free sensor would be wrapped around stents or diverters implanted to control blood flow in vessels affected by the aneurysms. To lower costs and speed up manufacturing, fabrication of the stretchable sensors uses aerosol jet 3D printing to create conductive silver traces on elastomeric substrates. The device could be the first demonstration of aerosol jet 3D printing to produce an implantable, stretchable sensing system for wireless monitoring, researchers said. "The beauty of our sensor is that it can be seamlessly integrated onto existing medical stents or flow diverters that clinicians are already using to treat aneurysms," said Woon-Hong Yeo, an assistant professor in Georgia Tech's George W. Woodruff School of Mechanical Engineering and the Wallace H. Coulter Department of Biomedical Engineering at Georgia Tech and Emory University. "We could use it to measure an incoming blood flow to the aneurysm sac to determine how well the aneurysm is healing, and to alert doctors if blood flow changes." The next phase will be able to measure blood pressure in the vessel along with the flow rates. "We will be able to measure how pressure contributes to flow change," Yeo explained. "That would allow the device to be used for other applications, such as intracranial pressure measurements." The research was reported Aug. 7, 2019, in the journal *Advanced Science* under the title "Fully Printed, Wireless, Stretchable Implantable Biosystem toward Batteryless, Real-Time Monitoring of Cerebral Aneurysm Hemodynamics."

MRI computing technique spots scar muscles of heart

Researchers at the University of Warwick in the U.K. have found a potential way for patients to undergo an MRI to diagnose cardiac disease without being exposed to gadolinium, which can cause kidney damage. A new 3D MRI computing technique developed by scientists at the school was detailed in the *Journal Scientific Reports* in an article titled "Hierarchical Template Matching for 3D Myocardial Tracking and Cardiac Strain Estimation." It focuses on Hierarchical Template Matching (HTM) technique, which involves: a numerically stable technique of LV myocardial tracking; a 3D extension of local weighted mean function to transform MRI pixels; and a 3D extension of HTM model for myocardial tracking problems. "This new MRI technique also takes away stress from the patient, as during an MRI the patient must be very still in a very enclosed environment meaning some people suffer from claustrophobia and have to stop the scan, often when they do this they have to administer another dose of the damaging gadolinium and start again. This technique doesn't require a dosage of anything, as it tracks the heart naturally," said Jayendra Bhalodiya, who conducted the research. The article appeared Aug. 28, 2019.

AI could use ECG data to assess overall health status

Doctors soon may be able to apply artificial intelligence (AI) to electrocardiogram (ECG) data to measure overall health status, according to new research published in *Circulation: Arrhythmia and Electrophysiology*. Using ECG data from about 500,000 patients, a type of AI known as a convolutional neural network was trained to find similarities among the input and output data. The neural network then was tested for accuracy on the data of an additional 275,000 patients by predicting the output when only given input data. Of note, the neural network estimated a patient's chronological age as higher after experiencing adverse health situations, such as heart attack, low ejection fraction and coronary artery disease, and lower age if they experienced few or no adverse events. "While physicians already consider whether a patient 'appears [their] stated age' as part of their baseline physical examination,

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Cardiology Extra

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the ability to more objectively and consistently assess this may impact health care on multiple levels," said study author Suraj Kapa, assistant professor of medicine and director for Augmented and Virtual Reality Innovation at Mayo Clinic in Rochester, Minn. "Being able to more accurately assess overall health status may help doctors determine which patients they should examine further to determine if there are asymptomatic or currently silent diseases that could benefit from early diagnosis and intervention. For people at large, an AI-enhanced electrocardiogram could better show there may be something going on such as a new health issue or comorbid condition that they were otherwise unaware of," continued Kapa. The researchers found that AI was able to accurately determine a patient's gender 90% of the time and the chronological age group of an individual with 72% accuracy. Additional studies with an overtly healthy population are needed to revalidate the neural network's determination. Additionally, gender was self-identified by patients and may not represent the sex of all individuals in the study. The findings appeared Aug. 27, 2019, in the article "Age and Sex Estimation Using Artificial Intelligence From Standard 12-Lead ECGs."

Hounds for the heart

Owning a pet may just keep your heart healthy, especially if that pet is a dog, according to the first analysis of data from the Kardiovize Brno 2030 study. The study assessed the cardiovascular health scores of pet owners overall to those who did not own pets. It then evaluated dog owners to other pet owners and those who did not own pets. "In general, people who owned any pet were more likely to report more physical activity, better diet and blood sugar at ideal level," noted Andrea Maugeri, a researcher with the International Clinical Research Center at St. Anne's University Hospital in Brno and the University of Catania in Catania, Italy. "The greatest benefits from having a pet were for those who owned a dog, independent of their age, sex and education level." The study first established baseline health and socio-economic information on more than 2,000 subjects in Brno, Czech Republic, from January 2013 through December 2014. Follow-up evaluations are scheduled for five-year intervals until 2030. The results have been published in the September 2019 edition of *Mayo Clinic Proceedings: Innovations, Quality & Outcomes* under the title "Dog Ownership and Cardiovascular Health: Results From the Kardiovize 2030 Project."