
Strategic Directions International, Inc.

INSTRUMENT BUSINESS OUTLOOK



Strategic Information for the Analytical & Life Science Instrument Industry

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The Top 30 Companies of 2017

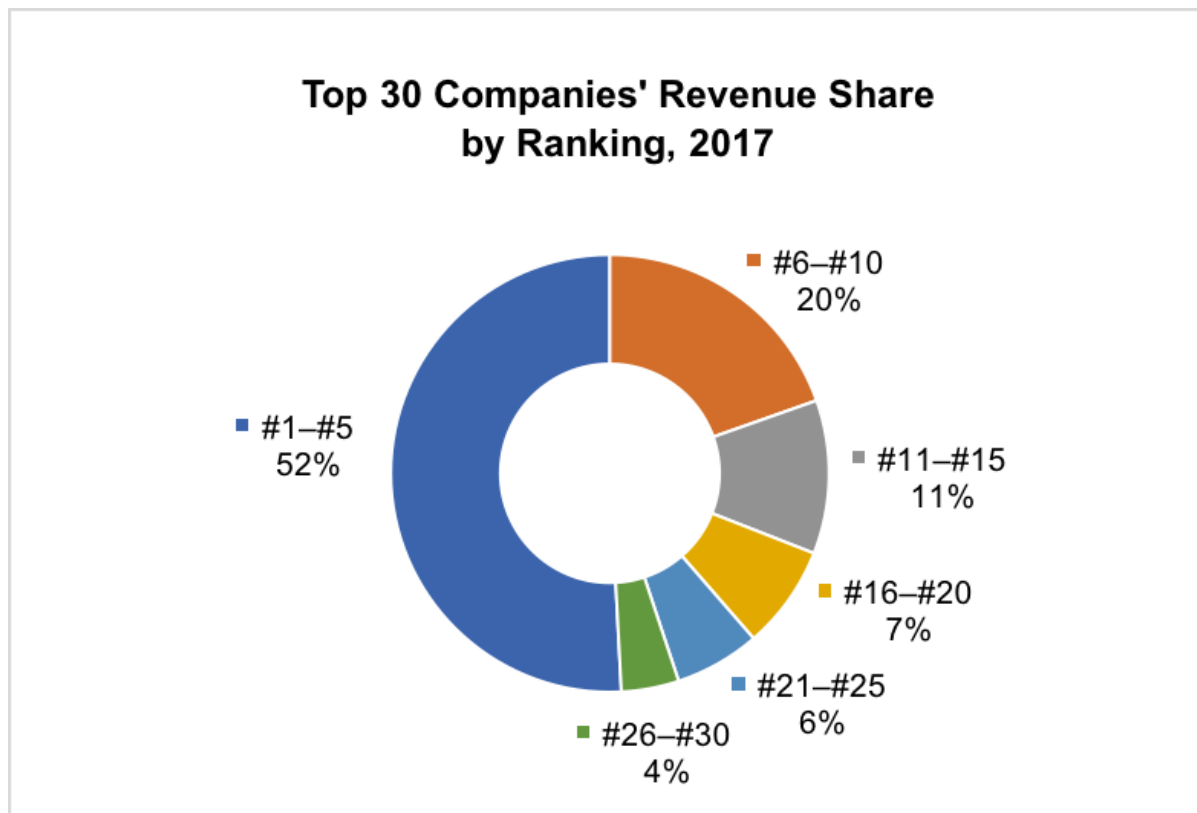
In 2017, the top 30 analytical and life science instrument, aftermarket and lab product businesses recorded \$40.7 billion in revenues in US dollars—counting only the sales of products in the 10 technology categories in *IBO*'s annual forecast issue and thus not the entire company's sales. In total, these businesses' revenues accounted for 74% of total industry sales last year.

**Top 30 Analytical and Life Science Instrument,
Aftermarket and Lab Product Firms of 2017**

Rank	Company	CY Rev. (Million)
1	Thermo Fisher Scientific	\$ 8,765
2	Agilent Technologies	\$ 3,692
3	Danaher	\$ 3,546
4	Merck KGaA	\$ 2,751
5	Illumina	\$ 2,457
6	Waters	\$ 2,309
7	PerkinElmer	\$ 1,622
8	Shimadzu	\$ 1,578
9	Bruker	\$ 1,508
10	GE	\$ 1,090
11	QIAGEN	\$ 1,058
12	Becton, Dickinson	\$ 1,026
13	Mettler-Toledo	\$ 868
14	Zeiss	\$ 859
15	Bio-Rad Laboratories	\$ 844
16	Hitachi High-Technologies	\$ 745
17	Roche	\$ 614
18	Sartorius	\$ 592
19	JEOL	\$ 574
20	AMETEK	\$ 558
21	Nikon	\$ 549
22	Spectris	\$ 538
23	Eppendorf	\$ 516
24	Olympus	\$ 501
25	Tecan	\$ 374
26	Promega	\$ 329
27	Oxford Instruments	\$ 322
28	Rigaku	\$ 319
29	HORIBA	\$ 273
30	Luminex	\$ 241

The figures presented in this article are based on revised estimates by **IBO** and thus are not directly comparable to prior years' top 30 rankings. The revised estimates are based on recalculations of counted sales based on updated information and adjustments.

All sales figures are presented in US dollars. Conversion of foreign currency sales into US dollars affected ranking. In particular, the weak yen against the US dollar accounted for lower sales growth for the Japanese businesses. In total, the top 30 list consists of 10 European businesses and 7 Japanese businesses.



As in previous years, Thermo Fisher Scientific was a dominant force, representing 16% of the total industry revenues, with its 2017 sales nearly triple those of the number 2 firm Agilent Technologies. Among the top 30 companies only, Thermo Fisher represented 21% of revenues.

Altogether, in 2017, the top 5 businesses represented 38% of industry revenues, and the top 10 represented 53%. Although the industry in general remains fragmented, the largest companies have steadily grown their share of sales. In fact, 12 of the top 30 businesses generate annual revenues of more than \$1 billion. Average sales for the top 30 was more than \$1.3 billion in 2017.

Each company has arrived at its position in part through major acquisitions completed in the last 12 years. These acquisitions include Thermo Fisher's 2006 purchase of Fisher Scientific, Invitrogen (see [IBO 4/15/13](#)) and FEI (see [IBO 5/31/16](#)). For Agilent, the company added \$1 billion in sales with the acquisition of Varian (see [IBO 7/31/09](#)). Among Danaher's many purchases were Leica Microsystems in 2005, SCIEX (see [IBO 9/15/09](#)) and Phenomenex (see [IBO 10/15/16](#)).

More notable is that each of the above companies have increased its sales. Besides strong high-growth markets such as MS and life science instrumentation, the companies have focused on expanding their consumables and service businesses, contributing to revenue growth. This is also true of most of the top 30 companies. In fact, among the top 10 businesses, only Danaher, Bruker and Shimadzu can be described as having relatively smaller aftermarket businesses.

The only top 30 businesses to record declining sales in 2017 following readjusted calculations were Oxford Instruments and HORIBA.

2018 SDi Global Assessment Report: The Laboratory Analytical & Life Science Instrumentation Industry

The definitive market reference tool for the analytical and life science instrument and lab product industry



The report covers 50+ individual instruments and related technologies with overviews categorized into 10 sections:

- Chromatography
- Life Science Instrumentation
- Mass Spectrometry
- Molecular Spectroscopy
- Atomic Spectroscopy
- Surface Science
- Materials Characterization
- Lab Automation
- General Analytical Techniques
- Lab Equipment

Each section also explores the current state of the competitive playing field and recent developments, and concludes with a 5-year market forecast.

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New Lab Announcements for Immunotherapy, Chemistry and Biomedical Research

In this article, the first part in **IBO's** biannual coverage of major new labs, we take a look at government, chemical and academic laboratory buildings planned for or under construction.

Government

US FY18 Budget Jumpstarts Construction on Chemistry Lab

Organization: Pacific Northwest National Laboratory (PNNL)

Location: Richland, WA

Lab Size: 120,000 ft² (11,148 m²)

Lab Cost: \$93 million

Estimated Opening Date: 2022, depending on continued DoE approvals for the project

With allocations for construction allotted in the FY18 US budget, the new world class chemistry lab at PNNL will focus on basic science and innovation, such as developing advanced catalysts and materials for new energy and

transportation technologies. Approximately 150 PNNL employees will have access to labs and work spaces, and the facility will also be able to house up to 50 visiting researchers collaborating on projects with PNNL researchers. The facility will include a next generation electron microscope, as well as a cutting edge NMR machine.

Cold Spring Harbor to be Home of New Biomedical Research Lab

Organization: Cold Spring Harbor Laboratory

Location: Cold Spring Harbor, NY

Lab Size: 26,000 ft² (2,415 m²)

Lab Cost: \$75 million

Estimated Opening Date: end of 2019

The new **Center for Therapeutics Research** will focus on biomedical research for advancing treatment for genetic diseases. The Center will allow dozens of scientists to collaborate on projects that integrate biology and genomics with chemistry and protein data. The goal of the lab is to ultimately develop advanced drug compounds to treat genetic diseases by targeting the underlying biological pathways.

Since 1890, the Cold Spring Harbor Laboratory has won eight Nobel Prizes for advances in molecular biology and genetics, and the establishment of the new research facility will help contribute to the Laboratory's legacy. "The faster you get these inventions, these discoveries to market, the more you help people," said New York Governor Andrew Cuomo. "You can literally save lives. And Cold Spring harbor has done that."

UK DRI to Establish Research Lab at University College London

Organization: UK Dementia Research Institute (UK DRI)

Location: London, UK

Lab Size: N/A

Lab Cost: £290 million (\$411.9 million)

Estimated Opening Date: 2024

The UK DRI is a collaborative project between the Medical Research Council, the Alzheimer's Society and Alzheimer's Research UK. Led by University College London (UCL), the UK DRI is redeveloping the Eastman Dental Hospital in London for advancing research into dementia prevention and treatment. The hub will be connected to the UCL Institute of Neurology in this new facility, housing over 500 neuroscientists. It will also provide space for public engagement.

"By 2020 we want to be the best country in the world for dementia care, and we also want to be best place in the world to undertake research into dementia and other neurodegenerative diseases," stated UK Business Secretary Greg Clark.

Chemicals

DuPont Spinoff Breaks Ground on New R&D Lab

Organization: Chemours

Location: Newark, DE

Lab Size: 312,000 ft² (30,000 m²)

Lab Cost: \$150 million

Estimated Opening Date: Early 2020

The **Chemours Discovery Hub** at the University of Delaware's Science, Technology and Advanced Research (STAR) campus in Newark will focus on process, product and application development to improve meeting market standards and needs. Chemours is a DuPont spinoff with brands such as Teflon.

The groundbreaking of the lab took place in January. "[The] groundbreaking goes far beyond a new building for Chemours," commented University of Delaware (UD) President Dennis Assanis. "As partners in innovation and economic development, Chemours and UD will build dynamic connections across business, education, research, learning and discovery."

Water and Waste Management Company to Open Specialty Chemicals Lab

Organization: SUEZ Water Technologies & Solutions (WT&S)

Location: Tomball, TX

Lab Size: 50,000 ft² (4,645 m²)

Lab Cost: N/A

Estimated Opening Date: August 2018

SUEZ W&T's new facility in Texas will serve as an R&D lab for specialty chemicals for the company's industrial segment. Projects will include developing new chemical and monitoring technologies. The state-of-the-art laboratory will include training facilities for engineers and scientists, and provide them with improved digital resources. The new lab will house scientists with expertise in various fields, such as metallurgical failure analysis, and chromatography and MS methods development.

The facility will also help strengthen the company's presence in the oil and gas industry by emphasizing global upstream and downstream applications. "The new facility will incorporate a multitude of different assets that help our analysis," said George DeLong, Global Analytical Laboratory leader at SUEZ WT&S. "[This includes] everything from simple pH instrumentation to very complex chromatography/mass spectrometers, scanning electron microscopes, x-ray diffractometers and more."

Academia

New Teaching and Wet Lab Facility in Florida

Organization: University of West Florida (UWF) Hal Marcus Campus of Science and Engineering

Location: Pensacola, FL

Lab Size: 52,790 ft² (4,904 m²)

Lab Cost: \$26.3 million

Estimated Opening Date: summer 2019

Connected to the University's Life Sciences Laboratory on its Pensacola campus, the new **Laboratory Science Annex** will provide extra classroom and wet lab space. The new building will be the location of 12 new teaching facilities for biology and chemistry programs, and will provide technology upgrades of equipment.

The Annex will also expand the university's research efforts, for which it receives over \$1 million each year in grants and contracts. "Breaking ground on the Lab Sciences Annex is a substantial step forward into UWF's next 50 years," commented Dr. George Ellenberg, provost and senior vice president.

Yale Continues Construction on New Science Building

Organization: Yale University

Location: New Haven, CT

Lab Size: 240,000 ft² (22,297 m²)

Lab Cost: [at least](#) \$200 million

Estimated Opening Date: fall 2019

At seven stories high, the new **Yale Science Building** will replace the JW Gibbs Laboratory, and will house the Department of Molecular, Cellular and Developmental Biology, as well as certain members from the departments of Molecular Biophysics and Biochemistry and Physics. The facility is expected to attract both science and non-science majors due to the open space and lecture halls.

The Building will have advanced technologies, such as specialized vibration-free labs for electron microscopy in its basement as well as a greenhouse for ecological research on the top floor. "I want Yale to be pre-eminent in the sciences and engineering," commented Yale University President Peter Salovey. "This is a building that is going to get us there. It's a new day on Science Hill."

University of Wisconsin Zeroes In on Chemistry

Organization: University of Wisconsin, Madison

Location: Madison, WI

Lab Size: 188,442 ft² (17,507 m²)

Lab Cost: \$123 million

Estimated Opening Date: 2020

Construction of a 10-story chemistry complex is underway. The building is a response to the growing demand for chemistry at the University, with enrollment in chemistry courses growing approximately 50% over the past two decades in STEM fields.

The budget will also cover renovations for the Daniels chemistry building. The renovated facility will include six teaching labs, extra classrooms, study areas and offices. Construction of this facility is slated for 2020, after the completion of the new chemistry complex, with opening expected by October 2022.

New Immunotherapy Research Center to be Established in Pittsburgh

Organization: University of Pittsburgh, and University of Pittsburgh Medical Center (UPMC)

Location: Pittsburgh, PA

Lab Size: 200,000 ft² (18,581 m²)

Lab Cost: \$200 million

Estimated Opening Date: 2020

The University of Pittsburgh and UPMC are collaborating on this multimillion project to accelerate immunotherapy research. The **UPMC Immune Transplant and Therapy Center** will emphasize research on transplantation, cancer, and aging and chronic diseases through innovations in drug development to treat chronic illnesses, rejections of transplantations and cancer.

The Center will conduct research and clinical trials. "This carries vividly the spirit of innovation and development," stated Jeffrey Romoff, UPMC president and CEO. "This is a period of radical transformation in health care. Here we

are looking at cutting edge research.”

Interdisciplinary Sciences Building to be Constructed in Washington

Organization: Gonzaga University

Location: Spokane, WA

Lab Size: 80,000 ft² (7,432 m²)

Lab Cost: \$48 million

Estimated Opening Date: 2019

After constructing a new athletic center, residential building and performing arts center, Gonzaga University is now focusing on the sciences. The **Integrated Science and Engineering** building will be home to an interdisciplinary collaboration between faculty from the College of Arts and Sciences, and the School of Engineering and Applied Sciences.

Along with engineering, students will be able to study subjects such as bioinformatics and materials science. Classrooms, project areas, teaching labs and research spaces will make up the new building.

New Medical Center for Complex Disease Research and Care to Open This Year

Organization: Mayo Clinic

Location: Jacksonville, FL

Lab Size: 190,000 ft² (17,652 m²)

Lab Cost: \$20 million

Estimated Opening Date: summer 2018

With a donation from the Harry T. Mangurian Jr. Foundation, the Mayo Clinic is currently constructing the **Dorothy J. and Harry T. Mangurian Jr. Building**, which will have 5 stories but the ability to expand to 12 stories. The building staff will provide cancer, neurological and neurosurgical treatments, with one floor dedicated to researchers. Two floors will house staff providing hematology and oncology care, and one floor will be used for neurology and neurosurgery care.

Due to the building housing the latest medical techniques and research, it has been touted as a “destination medical building,” where patients with complex diseases will receive treatment,

Agilent Completes Purchase of Lasergen

Santa Clara, CA 4/3/18—Agilent Technologies, a provider of solutions for the life sciences, diagnostics and applied chemical markets, has acquired the remaining 52% of NGS firm Lasergen that it did not own, for \$105 million. Agilent announced its initial investment in 2016 (see [IBO 3/15/16](#)). “Building a next generation sequencing workflow for clinical applications is a critical component to Agilent’s diagnostics strategy to fight cancer and constitutional diseases,” stated Jacob Thaysen, president of Agilent’s Diagnostics and Genomics Group. “We are focused on delivering patient-centric, actionable information for clinical decisions. Ensuring an integrated customer experience across all of our diagnostic modalities is essential and will become a key differentiator going forward.” Based in Houston, Texas, Lasergen has 45 employees.

This would add NGS technology to Agilent’s list of diagnostic techniques offerings, which currently include CGH, FISH/CISH, IHC and PCR. Agilent announced at the time of its initial investment the option to acquire the remainder of Lasergen for \$105 million. In total, Agilent paid \$185 million for Lasergen. The companies are working together

by integrating Lasergen's Lightning Terminators chemistry with Agilent's expertise in instrumentation and NGS workflows.

Single-Use Component Provider Acquired

Solon, OH 4/13/18— Saint-Gobain's Performance Plastics Life Sciences business, which supplies fluid handling solutions, has acquired Micro Hydraulics' pharmaceutical business for an undisclosed amount. Based in Ireland, Micro Hydraulics supplies and manufactures single-use components and systems for pharmaceutical and biopharmaceutical applications. "The acquisition of the Micro Hydraulics Pharma business is a continuation of our long-term strategy to expand our service and product offerings while increasing our localized presence for our customers," commented Steve Maddox, general manager of the Saint-Gobain Life Sciences business.

Micro Hydraulics provides a variety of fluid handling components for biopharmaceutical manufacturing, including for single-use processes. Products include Quattroflow pumps for LC and tangential flow filtration, tubing, valves and connectors.

Saint-Gobain's Life Sciences business consists of four divisions: Biopharmaceutical Systems, Medical Components, Filtration Technologies, Cell Therapy Solutions and Laboratory Products. The Biopharmaceutical Systems provides fluid management products for customized solutions, including single-use C-Flex biopharmaceutical tubing, in line with Micro Hydraulics' offerings.

Quanterix Buys Protein Microarray Firm

Lexington, MA 3/14/18; Lexington, MA 3/14/18; Washington, DC 3/19/18—Quanterix, maker of the Simoa technology for digitizing biomarker analysis, announced in its fourth quarter 2017 earnings release that it purchased Ashon BioSystems in January. The purchase price was \$3.2 million in cash and an additional payment of \$0.8 million based on post closing conditions, according to an SEC filing. Discussing the motivation for the purchase, Quanterix President and CEO Kevin Hrusovsky stated in the company's quarterly conference call, "The primary reason was the technology of planar printing, which is a complement to the bead technology that we have. And longer term, we believe that the planar technology will lead to a much more efficient point-of-care solution, which we think is a big piece of the long-term journey that we're on is to create a Point-Of-Care [POC] solution and form factor." He also noted Aushon BioSystem's existing CLIA-lab capabilities as a benefit. The company plans to use the lab to expand its pharmaceutical services business. Aushon BioSystems is expected to have no material impact on Quanterix's 2018 revenues. (For Quanterix's 2017 results, see [Bottom Line](#).)

Aushon BioSystem's Cira protein-biomarker immunoassay platform consists of plate-based assays, an array reader and a printer. Up to 12 analytes can be printed per well. The Ciraplex ULTRA Ultrasensitive Assays feature fg/mL detection levels for human cytokines.

*Discussing Aushon's menu of assays, Mr. Hrusovsky told **IBO**, "Aushon adds over 200 assays to the combined portfolio. The Aushon menu also has some additional species assays (mouse, rat, porcine, etc.) and has some additive multiplex cytokine panels, including a robust 10-plex. Many of these assays will be ported onto the Simoa platform." The number of Ashon Ciraplex ULTA Assays currently totals 11 and more assays are being added continuously, according to him.*

Asked how Quanterix plans to transition Ashon's technology to POC applications, Mr. Hrusovsky said, "The planar assay format of the Aushon technology lends itself to more flexibility in terms of developing POC instruments and platforms. Quanterix engineers and scientists are currently investigating several approaches to leverage the Aushon technology in POC instruments."

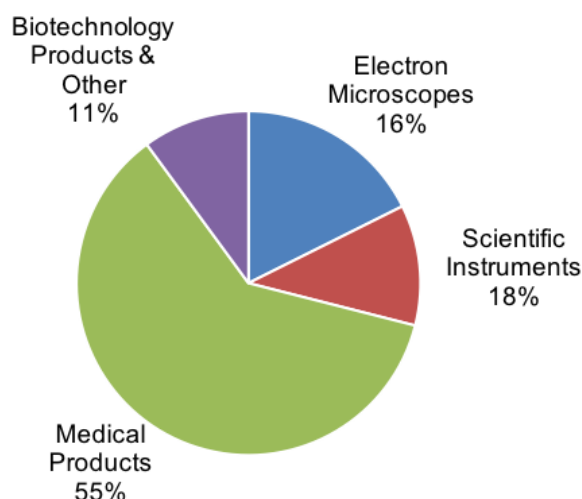
Fourth Quarter 2017 Results: Hitachi High-Technologies, Shimadzu, Spectris, Tecan

CY Q4 2017 Results									
Company	Revenues			Rev. Growth Summary			Adj. Operating Profit		
	Rev. (\$M)	% of Co. Rev.	Growth	Curr.	Acq./Div.	Org. Growth	(\$M)	% Growth	
Hitachi High-Tech. (Sci. & Med. Sys.)	¥42,361.0	27%	0.5%	0%	0%	1%	¥5,246.0	-27.8%	
Shimadzu AMI	¥56,800.0	62%	12.0%	3%	0%	9%	¥8,600.0	30.3%	
Spectris (Materials Analysis)	£464.9	31%	11.0%	4%	0%	7%	£83.1	9.1%	
Tecan (Life Sciences)	CHF 306.9	56%	9.5%	1%	5%	4%	CHF 50.5	10.5%	

Hitachi SMS Steady in Fiscal Third Quarter

Fiscal 2018 third quarter sales for Hitachi High-Technologies Science and Medical Systems (SMS) rose 0.5% to ¥42.4 billion (\$378.6 million at ¥112 = \$1).

Hitachi SMS Revenue Q3 FY18



Electron microscope sales remained flat at ¥6.8 billion (\$60.7 million), representing 16% of total SMS sales. Sales of Scientific Instruments, delivering the fastest growth in the segment, vaulted 52.9% to ¥7.8 billion (\$69.6 million). Scientific Instrument sales accounted for 18% of segment sales. Representing the largest amount of SMS revenue were Medical products sales at 55%. Medical Products sales, however, fell 9.7% to ¥23.2 billion (\$207.1 million) for the quarter. Biotechnology Products & Other revenue also decreased, sliding 4.3% to ¥4.5 billion (\$40.2 million).

For fiscal year 2018, Hitachi High-Technologies expects SMS sales to advance 1.0%, to ¥188.0 billion (\$1.68 billion). This represents a decrease of ¥0.5 billion from the previous projection. Annual operating profit is expected to fall 17.3% to ¥22.4 billion (\$200.0 million), unchanged from previous guidance.

Hitachi High-Technologies Science & Medical Systems Q3 FY18

	Rev. (¥B)	% Rev. Growth	% of Rev.
Electron Microscopes	¥6.8	0.0%	16%
Scientific Instruments	¥7.8	52.9%	18%
Medical Products	¥23.2	-9.7%	55%
Biotechnology Products & Other	¥4.5	-4.3%	11%

Shimadzu AMI Up Double-Digits in Fiscal Third Quarter

Shimadzu's Analytical and Measuring Instruments segment (AMI) delivered 12.0% sales growth in the fiscal 2018 third quarter, totaling ¥56.8 billion (\$507.1 million at ¥112 = \$1). Organically, AMI sales rose 8.8%, driven by strong MS and environmental measurement instrument sales, along with increased growth across most major regions.

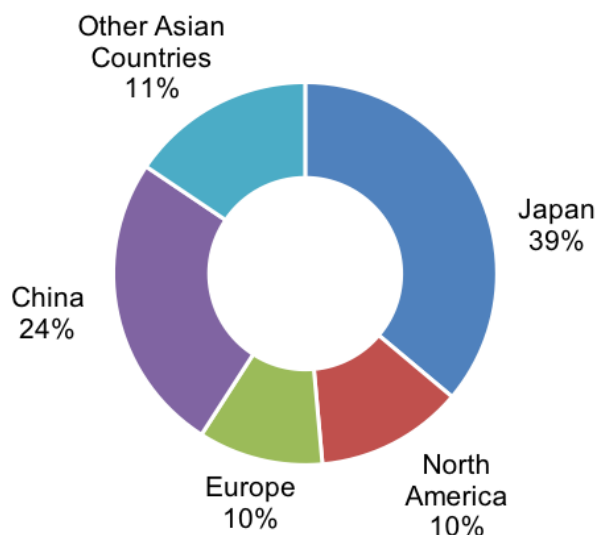
Shimadzu AMI Q3 FY18

	Rev. (¥B)	% Rev. Growth
LC	¥15.6	7.6%
MS	¥9.7	16.9%
GC	¥5.2	0.0%
Other	¥26.3	16.4%

By product line, LC sales increased 7.6% to ¥15.6 billion (\$139.3 million). LC sales for the quarter represented 28% of AMI revenue. MS sales delivered significant growth, advancing 16.9% to ¥9.7 billion (\$86.6 million). MS sales were driven by strengthened growth in the US, Japan and China. MS sales were also particularly strong in the food safety and environmental testing markets. GC sales remained flat, unchanged at ¥5.2 billion (\$46.4 million). Other AMI products lifted segment sales as well, increasing 16.4% to ¥26.3 billion (\$234.8 million)

Geographically, sales in Japan advanced 15.0% to ¥22.1 billion (\$197.3 million), driven by increased demand for LC products. Sales to the pharmaceutical and chemical markets also lifted Japanese sales. North American sales amounted to ¥6.0 billion (\$53.6 million), an increase of 16.3%. North American sales were primarily driven by strong MS and LC sales. Increased strength in the pharmaceutical and governmental markets supported North American sales even further. Sales in the European region grew 4.9% to ¥5.9 billion (\$52.7 million), supported by moderate MS sales. Sales in China remained strong as growth reached 16.8%, lifting sales to ¥14.1 billion (\$125.9 million). Chinese sales were driven by increased LC, GC and MS demand, along with strong food safety and government sales.

Shimadzu AMI Global Revenue Q3 FY18



For the full year 2017, Shimadzu expects its total company revenue to increase 9.5%, 8.3% organically, to ¥375.0 billion (\$3.35 billion). This represents an increase of ¥10.0 billion (\$89.3 million) over the previously projected figure. The company also adjusted the expected operating income upwards, increasing it by ¥1.0 billion from the previous projection to ¥41.0 billion (\$366.1 million).

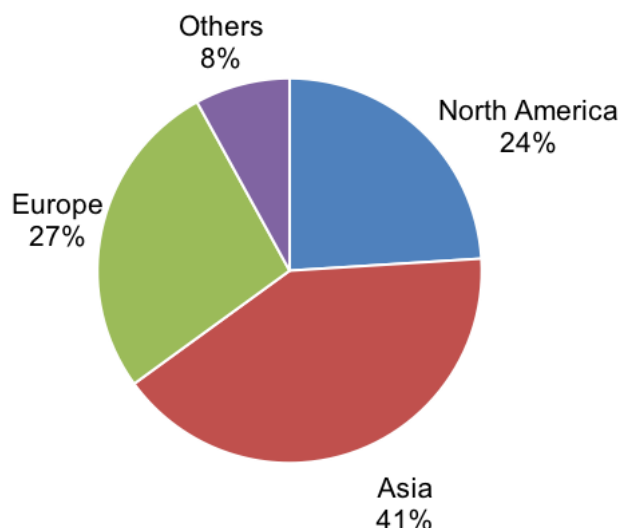
As for the AMI segment, Shimadzu expects sales to be ¥232.0 billion (\$2.07 billion), an increase of 10.9%. Operating income is projected to increase similarly as well, up 10.4% to ¥36.5 billion (\$32.6 million). However, operating margin is expected to fall 10 basis points to 15.7%.

Strong Finish for Spectris in 2017

Struggling in the first half of the year, Spectris delivered a solid recovery in the second half to drive full-year sales growth over double digits. Second-half Materials Analysis (MA) sales advanced 9.1% to £265.4 million (\$342.4 million at £0.77 = \$1), driven by increased sales to the pharmaceutical and metals markets. MA adjusted operating profit for the half was up 9.5%, finishing at £60.2 million (\$77.6 million).

As for the full year, MA sales advanced 11.0% to £464.9 million (\$599.7 million). In constant currency, sales rose 7.0%. MA sales for the year was primarily driven by strength in Asia and sales to the pharmaceutical market. However, weak demand in the semiconductor and academic research markets partially offset growth.

Spectris MA FY17 Revenue



Pharmaceutical and fine chemical sales increased for the year on a constant currency basis driven by strong growth in China and Japan. Sales to the metals, minerals and mining markets recovered from a weak 2016 and first half 2017 performance and delivered a significant growth in all major regions.

However, academic research sales were sluggish in 2017. With a slow start to the year, followed by just a moderate second half, academic sales declined in most major regions. India and the UK were the only exceptions, supported by improved funding levels.

Sales to the semiconductor, electronics and telecom market delivered strong growth, driven by China and South Korea. North America also added to the sales increase, driving semiconductor sales growth further. Demand for consumer electronics, along with rising IoT application usage significantly increased semiconductor spending and growth.

Partnering Sales Drives Tecan in Second Half

H2 2017

Second half 2017 sales for Tecan advanced 8.9% to CHF 295.1 million (\$308.7 million at CHF 0.96 = \$1). In constant currencies, sales rose 8.0%, driven by strong Partnering Business (PB) sales. PB sales for the half leaped 16.6% to CHF 126.4 million (\$132.2 million), an increase of 16.4% in constant currencies. PB sales were driven by significant growth in components, services and consumables demand

Tecan H2 FY17			
	Rev. (M)	% Rev. Growth	% of Rev.
Life Science	CHF 168.7	3.8%	57%
Partnering	CHF 126.4	16.6%	43%

Second-half Life Science Business (LSB) sales were moderate, increasing 3.8%, or 2.5% in constant currencies.

FYE 2017

Full-year 2017 sales for Tecan advanced 8.3% to CHF 548.4 million (\$573.6 million), driven by strong LSB sales, along with improved PB demand in the second half. In constant currencies, Tecan sales were up 8.0%, surpassing the company's expectations of 6% growth.

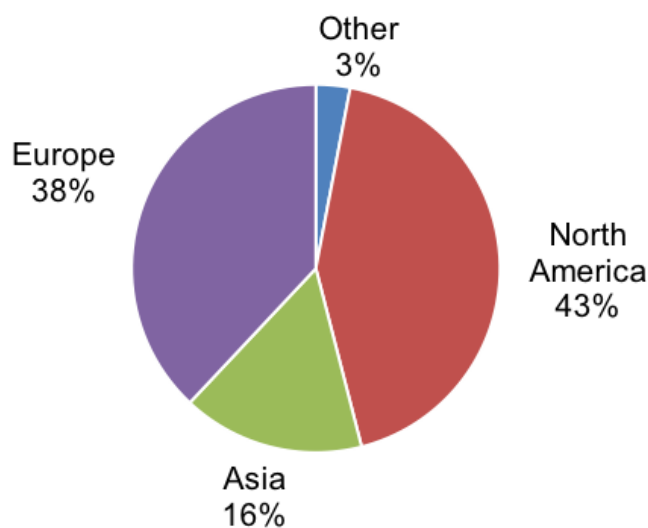
Tecan FYE 17			
	Rev. (M)	% Rev. Growth	% of Rev.
Life Science	CHF 306.9	9.5%	56%
Partnering	CHF 241.5	6.9%	44%

Sales for the LSB rose 9.5% to CHF 306.9 million (\$321.0 million). In constant currencies, LSB sales were up 9.0%. LSB growth was driven by strong service and consumables sales. Operating profit for the segment increased 10.6% to CHF 50.5 million (\$52.8 million). The segment's strong operating performance was due to solid sales growth and increased gross margin. Segment operating margin advanced 30 basis points to 15.9%.

PB sales were up 6.9% for the year, amounting to CHF 241.5 million (\$252.6 million). In constant currency, this was an increase of 6.7%. Segment growth was primarily driven by second-half strength in new instrument platforms and components sales. Recently acquired Pulsar Technologies also contributed to segment growth. Operating profit for the segment rose 26.2% to CHF 42.6 million (\$44.6 million), driven by increased efficiency and gross margins. Segment operating profit rose 2.7 percentage points to 17.9%.

Geographically, sales in Europe fell 3.6%, 3.0% in constant currencies, to account for 38% of total company sales. The decrease in European sales was primarily due to a tough comparison to 2016, for which revenue was boosted by PB sales. North American sales accounted for 43% of total sales, driven by both LSB and PB. Sales in North America rose 19.6% both on a reported and constant currency basis. Sales in Asia remained strong as both LSB and PB segments delivered double-digit growth for the region. Asian sales advanced 12.4%, 12.6% in constant currencies, to account for 16% of total sales.

Tecan Revenues FYE 17



FDA Furthers NGS Approval Process with Final Guidance

As discussed in March 31 issue of *IBO* (see [IBO 3/31/18](#)), recent FDA decisions have signaled the Agency's increasing attention to the regulation of NGS IVDs. Last week, these efforts continued as the FDA released two guidance documents for genomic testing. FDA Commissioner Scott Gottlieb, MD described the documents as providing "a modern and flexible framework to generate data needed to support the FDA's review of NGS-based tests, and give developers new tools to support the efficient development and validation of these technologies." The guidance documents finalize draft versions released in 2016. Although adherence to the guidance is not required by test makers, the guidelines indicate the FDA's position on the subject and its formation of future regulatory policies. The following article highlights pertinent aspects of the guidance but is not intended as a comprehensive summary.

Genetic Variant Databases for PMA Submissions

On April 12, the FDA released its final guidance on the role of genetic variant databases in the regulatory environment; specifically, the guidance regards the use of such databases to determine the clinical validity of genomic and genetic-based tests, including but not limited to NGS tests, as part of a premarket submission.

The guideline supports the use of such databases as part of premarket submissions, citing their conformity to professional guidelines and use of evidence from a range of sources, among other factors. It specifies how variant databases can be submitted to the FDA for recognition and the criteria for such recognition. The guidance applies to both open-access and commercial variant databases. The FDA is also considering the use of third-party reviewers for the databases, according to the document.

In particular, the guidance emphasizes public access to database procedures and operations, including data sources and standard operating procedures (SOPs). This is inline with the guidance's recommendations for ongoing database review and updates. As the guidelines states, "The FDA may also 'spot-check' assertions about genetic variants to assure they continue to be supported and that the genetic variant database continues to follow its SOPs for evaluation."

The guidance also specifies how database assertions can be used. "In order to be FDA-recognized, a genetic variant database should not include any recommendations regarding clinical treatment or diagnosis. However, an assertion that states that a variant is clinically significant as an actionable mutation may be found within an FDA-recognized genetic variant database."

Design, Development and Analytical Validation of NGS-based IVDs for Diagnosing Suspected Germline Diseases

This guidance document addresses NGS test development for whole-exome human sequencing and targeted human sequencing for diagnoses related to germline diseases (diseases resulting from inherited or de novo germline variants) in symptomatic individuals. In particular, the FDA views the guidance as assisting the development of consensus standards. By contributing to Special Controls, such standards could eventually aid in the submission of NGS-based germline tests as Class II devices under the De Novo process, opening the door for them to be used as predicate devices for 510(k) submissions. Beyond this, the FDA's stance suggests additional standards development, stating, "[the] FDA is particularly interested in the development of standards that address considerations beyond what is described in this guidance."

"...FDA believes that it may be possible, in the future, to develop special controls that could provide a reasonable assurance of the safety and effectiveness of NGS-based tests intended to

aid in the diagnosis of suspected germline disease, possibly under certain conditions of exemption, without the need for 510(k) premarket review.”

Furthermore, these developments could result in new test classifications, according to the guidelines, and, perhaps, no requirement for 510(k) approval. As the guideline states, “As the Agency gains more experience with these devices, FDA believes that it may be possible, in the future, to develop special controls that could provide a reasonable assurance of the safety and effectiveness of NGS-based tests intended to aid in the diagnosis of suspected germline disease, possibly under certain conditions of exemption, without the need for 510(k) premarket review.”

Among the submission requirement recommended to establish analytical validity are bioinformatics documentation, library preparation and enrichment, and multiplexing, among others. Notably, in regard to accuracy, “When clinical samples, cell lines or biosynthetic materials are not available, in silico constructed sequences containing known sequence variants of various claimed types (e.g., SNVs, indels, duplications, repeat expansions, CNVs, structural variants) may be used in addition to biological specimens to assess performance of the bioinformatics pipeline.” In addition, the guidance recommends documentation of variant annotation and filtering and how to present the test performance in labeling.

FT-ICR MS

Fourier transform-ion cyclotron resonance (FT-ICR) is an advanced form of MS characterized by unrivaled mass accuracy and resolving power. In fact, the systems that use this technology tend to be quite large, and are mostly found in R&D labs where a requirement for extremely high performance can justify the high cost.

In a typical MS, an inlet system sends an appropriate amount of analyte into an ion source, where the analyte molecules are converted into ions. The ions are then manipulated with a mass analyzer that separates them according to their mass-to-charge (m/z) ratio and focused onto a detector that can interpret the data signal.

In FT-ICR MS, the mass analyzer is based on ion cyclotron motion, where a force exerted by a uniform magnetic field onto an ion will always be perpendicular to the ion’s velocity. This phenomenon is known as the Lorentz force. Because of it, a uniform magnetic field will perpetually turn an ion, resulting in a circular orbit that goes uninterrupted until acted on by another force.

This circular orbit, where an ion goes around and around, is referred to as cyclotron motion, in which the frequency of rotation depends on an ion’s m/z ratio and the magnetic field strength. In fact, the performance of an FT-ICR system improves as the strength of the magnetic field increases, which is why the majority of them are designed with superconducting magnets, resulting in instruments that are both very large and very expensive.

In FT-ICR MS, the ions enter cyclotron motion surrounded by detection plates. However, ion detection by these plates is not possible unless the ions are close enough to them. To expand the radii of the orbit and enable proper detection, excitation plates that generate an electric field with opposing sine waves are placed parallel to the magnetic field, one above the ion orbit and one below. This accelerates the ions toward one plate and then the other.

As the frequency of the electric field approaches that of the cyclotron motion frequency, the ion’s motion will resonate with the electric field, increasing its kinetic energy and, in turn, the radius of its orbit. The ions can then be detected as they pass near the detection plates. The ICR cell in which these interactions are confined is known as a Penning trap.

The signal is collected by the detection plates as a sum of various sine waves that represent the superposition of all m/z signals in the time domain. A Fourier transform must be used to convert this signal into frequencies, thereby creating a mass spectrum of the sample.

First developed in 1974 at the University of British Columbia, FT-ICR mass analyzers have the highest-recorded mass resolution of any mass analyzer. As such, these instruments are ideal for analyzing very complex chemical and biological samples, even without the need for a separation method such as GC or LC. They can also be configured

with an additional mass analyzer, usually either an ion trap or quadrupole. Common applications include proteomics, metabolomics and lipidomics.

Despite the clear analytical advantages of FT-ICR, market adoption of the technology is inhibited by its high cost, large footprint and slow acquisition rates. This is especially the case as the technological advancement of alternative MS technologies slowly narrow the performance gap. Bruker dominates the market for FT-ICR MS through its solariX series, and there are very few alternative vendors. Thermo Fisher Scientific occupied a moderate market presence several years ago, but its products have since been discontinued. With a market of approximately \$60 million in 2017, market growth for this technology is expected to remain flat for the foreseeable future.

FT-ICR at a Glance:

Leading Vendor:

- Bruker

Largest Markets:

- Academia
- Biotechnology
- CROs

Instrument Cost:

- \$400,000–\$2,000,000

Energy

Global investments in renewable energy increased 2% in 2017 to \$279.8 billion, bringing cumulative investments in renewable energy since 2004 to \$2.9 trillion. 2017's rise in investments is largely due to the declining costs of wind and solar energy, allowing for megawatts of renewable energy equipment to be purchased for record low prices.

China was, by far, the leader in renewable energy investment in 2017, accounting for \$126.6 billion, or 45%, of the worldwide total. In 2017, 53 GW of solar energy units were installed in China, along with solar energy investments of \$86.5 billion. Investments in Mexico, Australia and Sweden soared in 2017, spiking a dramatic 810%, 147% and 127% to \$6 billion, \$8.5 billion and \$3.7 billion, respectively. Similarly, renewable energy investments in Egypt and the United Arab Emirates jumped almost 6-fold to \$2.6 billion and 29-fold to \$2.2 billion, respectively.

In contrast, renewable energy investments in the US decreased 6% to \$40.5 billion, with the decline mostly due to uncertainties regarding environmental policies. Europe's investments in renewable energy declined more dramatically, dropping 36% to \$40.9 billion. This is largely due to the post-Brexit landscape of Britain, as investments in the UK fell 65% to \$7.6 billion, as well as prolonged gaps between new offshore wind projects.

Source: [Frankfurt School-UNEP Collaborating Center for Climate & Sustainable Energy Finance](#)

Pharmaceuticals

According to results from the latest Pharmaceutical Research and Manufacturers of America's (PhRMA) annual membership survey, PhRMA member companies spent \$65.5 billion on total R&D in 2016, a 9.9% rise. Domestically, companies increased spending 9.0% to \$52.4 billion, while R&D spending abroad jumped 13.8% to \$13.1 billion. As a percentage of sales, domestic R&D accounted for 24% for member companies, and represented 20% as a percentage of total sales.

For human-use pharmaceuticals, members' domestic R&D expenditures totaled \$52.2 billion in 2016, accounting for

80% of total R&D spending, while \$12.9 billion, the remaining 20%, was spent on R&D abroad. Outside of human-use pharmaceuticals, R&D expenditures were for veterinary-use pharmaceuticals. By function, the majority of R&D spending was for Phase III R&D, which represented 28% of total R&D expenditures with \$18.3 billion spent in 2016.

Geographically, the US was home to the highest R&D expenditures in 2016 by members, with companies spending \$52.4 billion, accounting for 80% of total global pharmaceutical R&D. Other Western European countries, where members spent \$5.2 billion in 2016, ranked second. In the UK, PhRMA members spent of \$2.3 billion.

Source: [PhRMA](#)

Chemicals

The chemical industry has been on an upswing since its decline in 2016, with companies investing more in R&D in 2017. Collectively, 18 leading US and European chemical companies increased R&D spending in 2017 by 0.6% to \$9.9 billion. Although minimal, the increase is a welcome change after the 5.3% drop in R&D spending in 2016. Although chemical companies' R&D spending has risen and fallen over the past 10 years, it has largely remained the same; R&D spending in 2017 was essentially the same as it was in 2007, after adjusting for inflation.

In 2017, capital spending fell 5.8% for the 18 leading chemical companies, which is an improvement from the 15.3% drop in capital spending in 2016. Combined spending on R&D and capital projects for this group of companies in 2017 reached \$25.9 billion.

R&D budgets accounted for 36% of future-oriented spending in 2017. Companies such as DowDuPont, AkzoNobel and BASF have also been forming business incubators as an alternative to investing in startups. This is also contributing to the companies' R&D and innovation efforts, as it allows the companies to align themselves with possible disruptive technologies.

In 2017, the largest increase in R&D spending was by W.R. Grace, which increased it 10.2%, while the largest drop in R&D spending was by Air Products, for which it plummeted 56.1%.

Source: [Chemical & Engineering News](#)

China

China dominates global chemical revenue rankings, with sales of €1,331 billion (\$1,643 billion) in 2016, accounting for almost 47% of total global chemical investments. The country vastly surpasses other nations—for reference, the US, which ranks second, had 2016 chemical sales of €476 billion (\$587 billion).

By 2030, global sales of chemicals are forecast to reach €6.3 trillion (\$7.7 trillion), with China controlling the largest share at around 44%, of the market.

Chemical demand in China is growing rapidly, as well as in India and emerging countries, but is increasing at a slower pace in Europe and North America. Nonetheless, China is a large and attractive market for chemical suppliers and investments. The country is the EU's largest trading partner, representing approximately 9% of EU chemical exports.

In its 13th Five-Year Plan, the Chinese government outlined a strategic plan for the Chinese petroleum and chemical industry, with plans of becoming the world leader in the market through increased innovation and trade. The country's chemical companies have slightly shifted their focus onto specialty chemicals, but commodity chemicals are expected to remain a major import for the foreseeable future.

Source: [European Chemical Industry Council](#)

Japan

Last year's reported decline in Japan's scientific output (see [IBO 4/15/17](#)) has continued, with a further 3.7% drop in the country's contributions, adding to the 19.6% drop between 2012 and 2016. China's rapid rise in scientific research and publications has impacted Japan's ranking, as has the lack of scientific budgets, investments and resources in Japan in comparison to China.

Increasing research productivity is one solution to halting the continuing decline. When examining the country's performance in relation to its publication volume, as per *Nature's* weighted fractional count in the *Nature Index*, Japan ranks 5th in the world for top-quality scientific output.

On the other hand, Japan ranks 13th in regards to the amount of top-quality research per R&D dollars invested compared to other developed countries for which OECD R&D data is available. To tackle this, there has been a slow rise in university management reform, aimed at changing cultural attitudes toward academic research and improving management strategies. Key issues in academic research organizations include inflexibility in research projects and employee management.

The Japanese government plans to increase R&D spending from 0.65% to 1.0% of GDP by 2020, which would equal an investment of ¥900 billion (\$8 billion) over the next three years.

Source: [Nature](#)

UK

The UK has an established reputation of contributing heavily to European scientific research, with the region just recently winning 66 of the 269 European Research Council (ERC) awards. The next European initiative for scientific research will be the Framework Program 9 (FP9), which will have an estimated budget of £80-£100 billion (\$113.5-\$141.9 billion) over a seven-year period. However, although the UK can be a part of the initiative as an "associated country" such as Switzerland, Norway or Israel, the UK may not be able to participate in FP9. This is because the UK would have to invest a larger amount to be a part of FP9 post-Brexit than it does currently.

The UK Parliament's Science and Technology Committee has called for an agreement on science and research that would positively affect future negotiations with the EU. The deal on research is as important to national security issues, according to the Members of Parliament in the Committee, and is set to conclude by October this year.

The Brexit vote made the UK a less desirable place for researchers from EU member states due to perceptions of hostility towards foreigners and immigrants that contributed to a large decline in fellowship applications from the rest of Europe. However, Britain's economy had its strongest 6 months in over 10 years, according to recent economic reports, leaving the future of the region's collaborative projects with EU countries unclear.

Source: [Financial Times](#)

MS & LC/MS

Company Announcements

Publicly held **Protea Biosciences**, whose products included Laser Ablation Electrospray Ionization (LAESI) Mass Spectrometry, filed for bankruptcy in December 2017. The company announced that as a result of these plans, in November 2017, **George Washington University** terminated its exclusive right to use LAESI. President David Halverson resigned in December 2017.

Trajan Scientific and Medical and **Sierra Analytics** partnered in January to combine Sierra Analytics' HDExaminer software for Hydrogen-Deuterium Exchange (HDX) data analysis with Trajan's workflow automation expertise, including that of the **LEAP Technologies** business. Trajan will be a global partner and support provider for the software.

SCIEX announced in February a co-marketing agreement with **IROA Technologies**, a reagents and kits company specializing in metabolomics analyses. The companies will promote a unique labeling kit called the IROA Workflow Kit with SWATH Acquisitions based on next generation metabolomics and TripleTOF Systems.

Dr. Amy E. Herr, John & Lynne Dewar Lloyd Distinguished Professor of Bioengineering at the **University of California, Berkeley** and a **Chan Zuckerberg Biohub** Investigator, was named in February the recipient of the 2018 **SCIEX** Microscale Separations Innovations Medal and Award (previously the Arnold O'Beckman Award), for Current and Breakthrough Research in the Field of Electro-Drive Separations.

In February, **Thermo Fisher Scientific** announced that its LC/MS and IRMS workflows were used by the **Korea Institute of Science and Technology's Doping Control Center**, a **World Anti-Doping Agency**-accredited laboratory responsible for screening and identifying banned substances in athletes from around the globe during a major sports event in South Korea.

In 2017, **Microsaic Systems** revenues declined 59.8% to £342,514 (\$439,121), as the company switched its market focus from small molecule pharmaceuticals to bioprocessing, and to a solely OEM model. Adjusted operating loss increased from £2.7 million (\$3.5 million) to £3.2 million (\$4.0 million).

Microsaic Systems announced in March a commercial contract with the UK's **Centre for Process Innovation** focused on examining the potential of its Microsaic MS offering as an online, deployable tool for the elucidation of biopharmaceutical or biologic structure during the manufacturing or bioprocessing workflow.

In March, **Microsaic Systems** announced an agreement to combine its 4500 MiD MS detector with **Unimicro Technologies'** CE platform. The combined product will be sold directly by Unimicro in China.

Microsaic Systems signed a Head of Terms agreement in March with **Knauer** to integrate their respective MS and LC technologies. The systems will be sold directly by Knauer.

In March, **Bruker** entered into a co-development and co-marketing agreement with **Evosep** to integrate the Evosep One LC system with its timsTOF Pro ultrahigh resolution quadrupole TOF MS for high-throughput clinical proteomics.

In April, **Electrophoretics**, a subsidiary of **Proteome Sciences**, announced an amendment to the exclusive license and distribution agreement with **Pierce Biotechnology**, a part of **Thermo Fisher Scientific**, extending the current license to include intellectual property relating to a new class of higher-plex Tandem Mass Tags reagents currently in development.

Product Introductions

In February, **Hidden Analytical** introduced its new HPR-20 range of application-specific compact benchtop gas analyzers for dynamic measurement of in-process gas composition. Systems are routinely used in conjunction with thermal gravimetric analyzers.

SCIEX announced in February OptiFlow Quant Solution for easy, highly sensitive biomolecule quantitation. It comprises the new M5 Microflow LC with **Phenomenex** microflow columns and the new OptiFlow Turbo V Source. The new microflow LC has flow rate capabilities from 1–200 µL/min flow ranges, along with an auto-sealing injection needle, updated auto sampler with injector wash pumps and vial bottom sensing technologies. The OptiFlow Turbo V Source is a new single-click source that requires no physical adjustments for optimal ionization performance.

In March, **Advion** released the Open Port Sampling Interface designed for simple sampling of solids, liquids and sample preparation tips and fibers. Paired with the ESI of the **expression** Compact Mass Spectrometer, the product incorporates an open port of continuous small flowing volume of solvents directly into the MS.

Premier Biosoft released in March a database of glycans curated from published literature to facilitate rapid identification of N-glycans of rhEPO using tandem MS data.

JPT Peptide Technologies released in April The Human Proteome Peptide Catalog, calling it the first and most comprehensive online resource for validated reference peptides in MS- based proteomics. It provides fast access to more than 400,000 light and heavy proteotypic peptides.

Sales and Orders of Note

In March, **SGS** announced the installation of a second **SCIEX** 6500+ Triple Quadrupole MS for mycotoxins, pesticides and antibiotics testing at its Brookings South Dakota laboratory.

Life Science Consumables

Broad-based Companies

Company Announcements

SYGNIS announced that effective March 1, it had fully integrated its **Innova Biosciences**, **Expedeon** and **B.S. Scientific's** products and services under the Expedeon brand name. Expedeon serves the genomic, proteomic and immunology research markets.

Meridian Bioscience announced in March a realignment of its organizational structure. Operations are now conducted through two Business Units, Diagnostics and Life Science, both of which are supported by a global corporate team. Each of the two business units now has a consolidated sales and marketing team supporting the entire product portfolio. For the time being, CEO Jack Kenny will act as executive vice president of the Diagnostics Business Unit, in addition to his role as CEO. Lourdes G. Weltzien, PhD, has been promoted to executive vice president, Life Science, and will lead the Life Science Business Unit.

In March, **Streck** signed a three-year distribution agreement with **Van Xuan Medical Technology** for Vietnam.

Gene-based Consumables

Company Announcements

In February, synthetic DNA firm **Twist Bioscience** expanded its North American operations with a new office in the San Diego, California, area. Twist Bioscience is headquartered in San Francisco, California, with a second site in South San Francisco and an international office in Tel Aviv, Israel.

In April, **Twist Bioscience** completed a \$50 million private placement, bringing the total raised to \$250 million.

In March, **Horizon Discovery** announced that former CEO Darrin Disley (see [IBO 2/28/18](#)) is no longer on its Board.

Horizon Discovery partnered with **Genewell Biotechnology** to distribute diagnostic reference standards in China. Genewell will manufacture Horizon reference standards within China and distribute them as RUO products to Chinese diagnostic companies for use in their assay development program. Genewell will simultaneously pursue approval for the use of Horizon's reference standards with the **Chinese Food and Drug Administration**.

Horizon Discovery announced in March that its Glutamine Synthetase-Knockout CHO K1 cell line has been used as part of a successful Investigational New Drug filing with the US **FDA**.

In April, **Horizon Discovery** partnered with **The Pirbright Institute** to jointly work on a research program aimed at deploying cell engineering to increase the yields of livestock vaccines.

Gene editing company **Inscripta** closed a \$55.5 million Series C funding round in February. The round was led by **Mérieux Développement** and **Paladin Capital**.

DNA Script, a manufacturer of de novo synthetic nucleic acids, announced in April it will receive \$5.5 million in grants from the **European Commission's Horizon 2020 European Innovation Council** and **Bpifrance**. The financing will be received as subsidies and refundable advances. To date, DNA Script has raised \$24 million.

GSL Biotech and **VectorBuilder** partnered in April to make VectorBuilder's custom plasmids available through GSL Biotech's "Snap Gene" software.

In April, **Oxford Gene Technology**, a **Sysmex** company, promoted Dr. John Anson, executive vice president of R&D, to CEO. Former CEO Dr. Mike Evans was named a non-executive director. The company also named Paul Kenny to the new position of executive vice president of Regulatory and Medical Affairs. Previously, he served as head of Regulatory Affairs for immunodiagnostic company **The Binding Site**.

Product Introductions

In March, **Horizon Discovery** released the Edit-RTM CRISPRa arrayed crRNA (CRISPR RNA) libraries, the latest addition to its CRISPR activation (CRISPRa) reagent platform. Available as small gene families, bespoke collections, the druggable genome or human genome-wide collection, they enable native gene overexpression for high-throughput gain-of-function screening.

In April, **Thermo Fisher Scientific** introduced the Applied Biosystems MycoSEQ Mycoplasma Detection Kit, a fully integrated solution for real-time PCR-based mycoplasma detection. The MycoSEQ assay and method can be used for lot release by manufacturers in different therapeutic modalities.

Cell-based Consumables

Company Announcements

In February, **Emulate** entered into a strategic partnership with **Roche** for use of its Human Emulation System, a lab-ready system comprised of Organ-Chips, instrumentation and software apps, for testing of efficacy and safety of new antibody therapeutics and combination therapies.

Minerva Biotechnologies named **CellSystems** as a European distributor of its AlphaSTEM Naïve Stem Cell Culture System.

In March, **AMSBIO** agreed to distribute **Genea Biocells'** skeletal muscle differentiation product range to the academic community. Genea Biocells' skeletal muscle differentiation kit provides researchers with a unique tool to rapidly differentiate stem cells into functional myotubes in a reproducible fashion.

Samsara, an **Organovo** subsidiary, announced in March a supplier agreement with **Lonza Bioscience** for its human cell products, including specialized human liver cells. The agreement is Samsara's single largest contract to date.

In March, **Elixirgen Scientific** announced an agreement allowing it to produce and distribute cells differentiated from the **California Institute for Regenerative Medicine's** (CIRM) hPSC repository. When applied to CIRM's hPSC bank, Elixirgen Scientific's Quick-Tissue differentiation technology will be able to provide relevant tissues for any of the 1,600 cell lines.

In March, **BioIVT**, a provider of high-quality biological specimens and value-added services, acquired cell-based assay provider Ascendance Biotechnology. **Ascendance Biotechnology's** products include Hepregen HepatoPac, HepatoMune and HepatoStem liver cell and stem cell product lines.

Product Introductions

In March, in partnership with **Multiclonal Therapeutics**, **Bio-Techne** introduced the MimEX GI human tissue-model system for generating 3D gastrointestinal tissue on a 2D surface using adult groundstate stem cells. The launch includes a licensing program for its use in commercial applications.

Protein-based Consumables

For the six months ending December 31, 2017, **Abcam** revenues grew 9.8%, 11.2% in constant currency, to £112.5 million (\$150.0 million) (see [IBO 3/31/18](#)). Catalogue revenues rose 11.5%, 10.0% in constant currency, to £105.2 million (\$140.3 million). For Catalogue revenue, recombinant antibody sales rose 21.1%, 22.8% in constant currency, to £22.4 million (\$29.9 million), and Immunoassay sales grew 20.7%, 23.4% in constant currency, to £7.0 million (\$9.3 million). Customer Product & Licensing revenue rose 5.8%, 7.8% in constant currency, to £7.3 million (\$9.7 million). Adjusted operating profit rose 9.8 % to £39.0 million (\$52.0 million). The company raised its fiscal year guidance to 11% revenue growth, including the impact of the Spring Bioscience transaction (see [IBO 1/31/18](#)).

In March, **Thermo Fisher Scientific** announced an agreement with the Montreal **Neurological Institute of McGill University** designed to accelerate the understanding of neurological disease by focusing on about 30 proteins associated with Parkinson's disease, amyotrophic lateral sclerosis, hereditary spastic paraplegias, epileptic encephalopathies and ataxias. As part of the study, Thermo Fisher will generate rabbit recombinant antibodies using its ABfinity antibody technology for proteins that investigators at the Institute and other scientists have associated with particular neurological diseases. The research will result in a set of highly validated reagents that will be made available to the scientific community.

In April, **Cell Signaling Technology** (CST) opened an office in Shanghai, China, tripling office and warehouse space in the country. The new space includes CST's Global Innovation and Funding Academy.

Enzyme product firm **Genovis** named **Chayon Laboratories** as a distributor for South Korea.

Product Introductions

In March, **TGR BioSciences** announced the global availability of Alpha Terbium *SureFire Ultra* assay kits. These new kits can be easily combined with existing AlphaLISA *SureFire Ultra* kits to provide high-throughput capability of multiplexed phosphoprotein detection in a homogeneous assay format. The kits combine **PerkinElmer's** homogeneous Alpha (Amplified Luminescent Proximity Homogenous Assay) detection chemistry with TGR's CaptSure Multiplex technology to allow the measurement of two phosphoprotein targets in each assay well in a mix-and-read format. The portfolio is available exclusively through PerkinElmer.

Bioprocess Analysis

Company Announcements

Rexgenero, a clinical stage regenerative medicine company developing advanced cell-based therapeutics with a focus on Critical Limb Ischemia, announced that it will receive £1.4 million (\$1.9 million) in funding for a £1.8 million project (\$2.5 million) from **Innovate UK**. The project is entitled "Cost-driven process redesign, automation and scale-out for commercial manufacture of REX-001 therapy." Partners in the consortium are the **Cell and Gene Therapy (CGT) Catapult**, **TrakCel** and **Fisher Bioservices** (part of **Thermo Fisher Scientific**).

In January, **Pall**, a **Danaher** company, announced a newly named business unit, Pall Biotech, within Pall Life Sciences. Pall Biotech's portfolio consists of standard configurable single-use, stainless steel and hybrid technologies for fed-batch and continuous processes across upstream, downstream, and formulation and filling applications.

In February, **Pall** announced the opening of the \$2 million **Nanyang Polytechnic Centre of Excellence** (NYP) for biologics manufacturing in Singapore. The integrated training center will serve 300 NYP School of Chemical and Life Sciences students annually.

Pall announced in February the opening of an expanded office in Hoegaarden, Belgium. The facility includes 21,528 ft² (2,000 m²) of new office space, in addition to R&D, customer demonstration and manufacturing space. The facility, with over 300 employees, combines three Belgian locations.

In April, **Merck KGaA** partnered with **Oxford University's Jenner Institute** to develop more robust and scalable vaccine manufacturing processes. The partners will improve the manufacturing process for adenovirus vaccines using Merck products, systems and technologies on a real-world feed stream.

Product Introductions

In March, **Sartorius** launched the ambr 250, a high-throughput automated parallel bioreactor system, specially designed for rapid cell culture-perfusion process development to optimize production of therapeutic antibodies. It combines 12 or 24 single-use perfusion mini bioreactors (100–250 mL working volume) with associated single-use perfusion components, all controlled by one automated workstation.

Sales and Orders of Note

GE Healthcare announced in January that **Clover Biopharmaceuticals** has chosen its FlexFactory, a biomanufacturing platform based on single-use technologies, for its new facility in Changxing, Zhejiang, China. The biomanufacturing facility, which will be operational in the latter half of this year, includes two 2,000 L bioreactors from GE.

In March, **Sartorius Stedim Biotech** announced that **ABL Europe** has selected the company as its primary supplier of single-use systems. Sartorius Stedim Biotech delivered a comprehensive GMP viral vector manufacturing package solution that included single-use bioreactors and an automation platform for normal flow filtration, tangential filtration and mixing. ABL Europe provides dedicated viral vector GMP manufacturing services for oncolytic, vaccine and gene therapy projects in all stages of clinical development through to commercial launch.

Contract development and manufacturing organization **WuXi Biologics** announced plans in March to install **ABEC's** 4,000 L custom single-run disposable bioreactors at its new commercial manufacturing facility in Wuxi, Jiangsu, China.

Process Analysis

Company Announcements

In January, **Environnement** debuted a new brand, envea. The brand intends to provide a more complete vision of the firm's monitoring solutions, together with its high-added value services. The new organization consists of three core businesses: Ambient Air, Industry & Process, and Emissions. The company aims for 2020 annual revenues of €100 million (\$112 million). Current revenues total nearly €80 million (\$90 million).

The [Bartlesville Examiner-Enterprise](#) reported in January that **Siemens** plans to close its Bartlesville, Oklahoma plant, which makes GCs, and transfer operations to a facility in Houston, Texas. Approximately 150 people worked at the Bartlesville plant in 2015. The plant is expected to close by fall 2019.

In March, **Polytec** named **Quantum Design** as a Japanese distributor of its process NIR Systems.

Product Introductions

In February, **Metrohm Process Analytix** launched the 2026 pH Analyzer, an economical online process analyzer. Designed for industrial processes and wastewater streams, it is available in several application-specific configurations for monitoring up to two process streams.

JP3 Measurement launched in March the NIR optical spectroscopy-based Verax SSG (gas analysis) and SSL (liquid analysis) single-stream online oil and gas analyzers. Verax systems measure with flow cells directly in the fluid stream at operating pressure and temperature, requiring no sample transport, sample selection or conditioning systems.

Sales and Orders of Note

In March, **Yokogawa Electric** announced an order for 190 Yokogawa GC8000 process GCs, its largest order to date for the GC8000. The GCs will be used in the first phase of **Zhejiang Petrochemical's** project to construct an integrated refinery and petrochemical production complex at a new industrial site in the Zhoushan Archipelago, China. The first phase is expected to be completed and put into production by the end of December.

Reported Financial Results

\$ in Millions USD	Period	Ended	Sales	Chg.	Op. Prof.	Chg.	Net Prof.	Chg.
MaxCyte	H2	31-Dec	\$7.8	14.3%	(\$5.3)	-200.1%	(\$5.6)	-170.2%
MaxCyte	FYE	31-Dec	\$14.0	14.0%	(\$9.3)	-241.2%	(\$9.9)	-196.4%
Pressure Biosciences	Q4	31-Dec	\$0.5	19.8%	(\$1.3)	-12.0%	(\$2.8)	NM
Pressure Biosciences	FYE	31-Dec	\$2.2	13.4%	(\$4.6)	-24.4%	(\$10.7)	-295.8%
Other Currencies (in Millions)								
Immuno-Biological Laboratories	Q3	31-Dec	¥171.0	6.2%	¥27.0	68.6%	¥28.0	68.2%
Immuno-Biological Laboratories	9 mo.	31-Dec	¥504.0	-1.4%	¥66.0	63.9%	¥68.0	65.8%
Olympus (Scientific Solutions)	Q3	31-Dec	¥25.4	9.7%	¥2.3	9.4%	NA	NA
Olympus (Scientific Solutions)	9 mo.	31-Dec	¥70.0	10.2%	¥3.5	88.4%	NA	NA
Renishaw (Metrology)	H1	31-Dec	CHF 264.3	17.7%	CHF 63.6	45.7%	NA	NA
Renishaw (Healthcare)	H1	31-Dec	CHF 15.2	12.6%	-CHF 1.9	68.6%	NA	NA
ReproCELL	Q3	31-Dec	¥241.0	-30.0%	¥236.0	-52.3%	¥217.0	NM
ReproCELL	9 mo.	31-Dec	¥687.0	-20.2%	¥772.0	-23.7%	¥652.0	-19.9%

NA = not available, NM = not meaningful

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