

Strategic Information for the Analytical & Life Science Instrument Industry

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Companies Focus on Comprehensive Solutions for Wastewater Testing in China

The release of China's 13th Five Year Plan, focusing on 2016–2020, accented the country's efforts to address the environmental issues arising from water pollution, with the Plan <u>indicating</u> a goal of spending 0.75% of GDP on improving wastewater treatment. The strategies within the Plan have helped create additional opportunities for investments in and applications to improve wastewater testing and monitoring, enabling leading water lab testing



technology companies such as Hach and Xylem to further strengthen their presence in the nation.

China Water Risk (CWR) is a nonprofit initiative focused on highlighting the environmental and business risks of the water crisis in China, and finding solutions to enable more sustainable uses of water resources. Established in 2010 in its pilot form as the Asia Water Project, CWR was formally launched in 2011, and works alongside industry experts and investors to provide a plethora of information, data, case studies and research on water issues in China.

Yuanchao Xu focuses on sectoral and regional water and climate risk assessment at CWR, as well as China regulatory risk interpretation. According to Mr. Xu, China's 13th Five Year Plan incorporates strategies to addresss wastewater issues, such as new systems utilizing real-time data that are planned for the future. "The total budget for urban wastewater treatment facilities in the 13th Five Year Plan is CNY 564 billion (\$82.7 billion)—over half of this is allocated for the drainage network (new and retrofit), and around 35% is for new wastewater treatment facilities and upgrade of existing plants," said Mr. Xu. He noted that monitoring and management comprises less than 1% of the total budget. "Nevertheless, the 13th Five Year Plan does propose to establish a holistic urban wastewater discharge and treatment system which comprises almost seven hundred monitoring stations, [and] a lion's share of these (>90%) will be city- and county-level stations. A real-time monitoring system to promote the application of big data in environmental protection is also planned," he explained.

Additionally, Mr. Xu highlighted China's strategy of engaging the public to participate in maintaining water quality through its river chiefs program. Established in 2007 by the government of Wuxi city after the cyanobacteria pollution issue in Lake Taihu, the river chiefs program makes government officials responsible for protecting bodies of water. There are four levels to the river chiefs mechanism: provincial, urban, county and township, with each principal river chief assigned to be in charge of the water bodies in their jurisdiction. "It is important to remember that China is involving the public in monitoring its water bodies," said Mr. Xu. "The speed of growth of this network is astounding—as of August 2017, there were 200,000 river chiefs appointed; by December 2017, this expanded to 900,000."

In March, the Chinese government restructured the science research funding body, which affected organizations such as the National Natural Science Foundation (see *IBO* <u>3/30/18</u>). "The ministry reform in March is aimed at improving management efficiency and doing away with overlapping responsibilities," said Mr. Xu. "So instead of managing air, water and soil pollution separately, the newly established Ministry of Ecology and Environment (MEE) will now address these issues together as one whole ecological system." This attempt at reducing red tape extends to water pollution management as well, Mr. Xu indicated. "Groundwater pollution control used to come under the Ministry of Land Resources, but these responsibilities have been moved into the MEE. Surface and groundwater will now be managed under one umbrella," he explained. "We expect the budget related to such activities to thus be reallocated accordingly; however, it is still too early to say whether the total budget allocated to both surface and groundwater pollution control will be affected. This will also apply across other functions."

Opportunities Across Segments

Wastewater monitoring generally comprises categories such as testing for organics, nutrients, solids or physical properties. According to Mr. Xu, it's difficult for CRW to ascertain which category is the fastest growing or has the highest funding level due to the fact that, as he explained, "discharge requirements across categories differ from sector to sector."

"While data integrity is also a high priority in other regions, there are some regional differences, and so Hach has had to make some product modifications to meet the needs of customers in China."

In contrast, leading water technology instrument companies, such as Hach and Xylem, are able to gauge rising trends based on customer demand. According to Charles Pan, general manager of Xylem Analytics, there is a rise in demand related to nutrients testing. "Because of China water resource eutrophication, the total nitrogen (TN), total phosphorous (TP), nitrate, nitrite, etc. parameters need to be tested and monitored, both for the online and lab side," he explained. "Also, the government increased the discharge Standard of Pollutants for Urban Wastewater Treatment Plant (GB 18918-2002) from Class 1 standard B to standard A." To comply with the new regulations,



many wastewater treatment plant-upgrade projects needed to add new instruments in order to test the new parameters. "For example, in the discharge outlet, TP and TN testing now are necessary," stated Mr. Pan. "So this category is [among the] fastest growing over the years."

Kevin Klau, president of Hach, echoed Mr. Pan's sentiments. "Globally, there is a trend that reveals nutrient monitoring, especially TN and TP, is growing at above-average rates," he explained. "Recently in China, the government has placed a high priority on TN/TP online monitoring for surface water. Meanwhile, organics, especially total organic carbon (TOC) and chemical oxygen demand (COD) are also priorities both in China and in many other regions."

In terms of wastewater testing segments, both municipal and industrial wastewater testing are robust end-markets. "In China, our experience is that both segments are growing at solid annual growth rates, though we see industrial wastewater growing faster," explained Mr. Klau. "Our experience is that we see the government and provinces in China requesting wastewater-discharge entities to take the cost ownership of wastewater monitoring and testing."

Xylem has had a similar experience in China. "From the market volumes' aspect, the municipal market volume is obviously much bigger than the industrial market by about 2-3 times, but from the new-growth market, the industrial market is increasing much faster," explained Mr. Pan. This is also likely due to the 2015 Water Pollution Prevention and Control Action Plan (also known as the Water Ten Plan), which focuses on protecting Chinese water bodies.

As Mr. Pan explained, many water protection standards were established as part of the Water Ten Plan, including over 10 related standards for industrial wastewater treatment, more than 30 water pollutant discharge national environmental standards and over 20 local environmental water pollutants discharge standards for industry development. "Both government and industry enterprises pay attention to the industrial wastewater [segment], and the main industry wastewater market is located in the Eastern and Southern regions of China, which occupies more than 60% [of the market]," he said. "For the testing initiatives' topic, most of the time the municipal wastewater testing will get funding from government, [while] industrial wastewater testing needs get funded by enterprises themselves."

Both Mr. Pan and Mr. Klau indicated that wastewater testing labs in China can choose their products and instrumentation from many qualified suppliers, as opposed to their choice of vendors as being federally mandated. "Usually the government is just responsible to check and approve for big project funding. For treatment plants' lab equipment purchasing, the government will not be involved in the purchase process," said Mr Pan. "The testing labs themselves will make the bid to find the right products and instruments according to different companies' branding, quality, technical parameters, service and price, etc."

Sharpening a Customer-Oriented Focus

Service, support and training needs for wastewater testing in labs in China are generally similar to those in the US or other countries, although some companies may tailor their instrumentation to provide a more comprehensive customer experience. As Mr. Klau explained, Hach has made certain modifications its products in order to optimally serve its Chinese customers. "In China, the Dynamic Control on wastewater discharge (WWD) required by regional environmental protection administrations (e.g., in provinces of Shandong, Jiangsu and Hubei) request special functionality of WWD in-process instruments to ensure data integrity." He added, "While data integrity is also a high priority in other regions, there are some regional differences, and so Hach has had to make some product modifications to meet the needs of customers in China."

Furthermore, Mr. Klau pointed out, there is a trend in China in which many customers prefer in-process instruments that are installed in uniform cabinets for influent/effluent water quality online monitoring. "Companies like Hach either do this for them from the factory, or we work with operating companies and channel partners to provide the in-process instruments in the cabinets," he explained. "While customers in other regions often prefer equipment installed into cabinets as well, it tends to be more application specific (i.e., instruments installed in a power plant for water quality monitoring is installed in cabinets a high percentage of the time)."

"Serving customers better is a key part of our overall strategy."

Additionally, there can be a difference in the use of reagents. "In China, with different regulations, the customers of wastewater testing labs often mix their own reagents by following national standards, so as to ease the data comparison between customers' lab testing data and the data from government supervisors," noted Mr. Klau. "In other geographies, it is typical that customers purchase the chemistries from companies like Hach more often, as testing methods are often more aligned between regulatory agencies and technology providers."

Most of Xylem's products are manufactured in the US or Europe, Mr. Pan stated, which makes it more difficult to modify. However, Xylem is focused on providing a comprehensive solution in regards to service, support and training that emphasizes optimal customer support. "We set up comprehensive service abilities in China, and we have authorization service centers," he said. "This service capability can cover most of our customers' different requirements and improve customer satisfaction."

Additionally, Mr. Pan elucidated, as a large water technology company, Xylem has the capability to offer many resources to its customers and opened a regional integration center in China to provide optimal customer service. "We have a strong capability to provide total solutions, we have an abundant product portfolio, we have deep technical know-how and we have many different brands with long histories," he said. "All of these highlights help us meet most of [our] Chinese wastewater testing customers' needs."

Ultimately, providing customers with the best service and solution possible is a priority for both Hach and Xylem. As Mr. Pan stated, Xylem focuses on a "customer first" philosophy. "We can design and develop instrument system solutions to meet local customer requirements," he said. "In a word, serving customers better is a key part of our overall strategy."

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On-chip Cell Sorters

The sorting and isolation of specific cells from heterogeneous mixtures is a crucial task in life science research, clinical diagnostics and therapeutics. Initially developed in the late 1960s, fluorescence activated cell sorting (FACS) instruments are specialized flow cytometers that sort and collect cells based on specific fluorescent emissions from antibodies, probes and tags. As cell sorting technology evolved, magnetic activated cell sorting (MACS) was introduced, which operates on the same principles as FACS, but uses magnetic probes and tags to sort and collect cells. Modern cell sorters are capable of high-throughput separation of tens-of-thousands of cells per second.

Conventional FACS- and MACS-based cell sorters pose several challenges for users. As cell suspensions flow through the instrument, they are pressure forced through a nozzle to aerosolize and separate cells into individual, charged droplets, which are laser-scanned, and droplets containing the cells of interest are diverted and separated based on charge. The aerosolizing process creates shear-stress, which may damage and decrease the viability of sorted cells. Aerosolized particles also create biohazardous exposure risks for users. Because the cell suspensions must travel through the instruments, there is the potential for contamination, even when proper cleaning protocols are followed. Finally, as a result of the complexity, large footprints and high costs of most cell sorter instruments, they are typically incorporated into core facilities rather than individual labs, creating accessibility and availability barriers.

Recent advances in cell sorting technology have addressed these issues with the introduction of on-chip sorting. The heterogeneous cell mixture to be sorted is loaded into a sterile, single-use cartridge, within which all cell sorting functions are performed. Since the cells do not flow through the instrument itself, the risk of contamination is greatly reduced. Instead of aerosolizing the cell suspension, fluorescent-tagged cells flow through microfluidic channels. This mechanism removes aerosol-exposure risk and is much gentler on the sorted cells. Each supplier utilizes a different mechanism for diverting the target cells of interest into collection channels. On-chip cell sorters are much smaller than their conventional counterparts. They are small enough to place into a cell culture hood or on a benchtop, making them more accessible to individual labs.

However, microfluidics-based cell sorters do have some limitations compared to conventional cell sorters. Since they are smaller, they generally use fewer lasers than conventional sorters. This narrows the absorbance wavelengths they are able to detect, limiting the number of parameters that the instruments can analyze. They are also not as fast as conventional cell sorters, some of which can reach throughputs of up to 200,000 events/second. The volume of cells that can be processed in one run in limited by the capacity of the cartridges. Because the cartridges are single use, there is an additional consumables expense that is not associated with conventional cell sorters.

In the past few years, several companies have brought microfluidics-based cell sorter instruments to the market. Highlighted here are three recently introduced models.

Selected Microfluidics-based Cell Sorter Instruments						
Manufacturer	NanoCellect Biomedical	Miltenyi Biotec	Sony Biotechnology			
Instrument Name	ent Name WOLF MACSQuant Tyto		MA 900			
Launch Date	Jun-16	Dec-17	Aug-18			
Sorting Speed	24 μL of sample/minute	Up to 55,000 cells/second	Up to 30,000 cells/second			
Absorbance/Excitation	488 nm	405 nm, 488 nm, 638 nm	405 nm, 488 nm, 561 nm, 638 nm			
Detection Parameters	5	10	14			
Sorting Mode	Three-way	Two-way	Four-way			
Single-cell Dispensing	N1 Single Cell Dispenser (add-on)	cellenONE X1 (add-on)	On-board			
Separation Mechanism	Piezoacoustic actuator	Microvalve controlled by magnetic pulse	Information not available			





NanoCellect WOLF Cell Sorter



Miltenyi MACSQuant Tyto





Sony Biotechnology MA900

Second Quarter Revenue Growth Propelled by Both Industrial and Life Science Sales

Calendar year second quarter sales for publicly held analytical and life science instrument and lab products companies were strong overall. Businesses that reported a double-digit increase in organic revenues included Bio-Rad Life Science, Bio-Techne, Illumina and PerkinElmer Discovery & Analytical Solutions (DAS). Sales for companies performed as expected with a slight uptick in fiscal full year expectations, as Agilent Technologies, Bruker, Ilumina, PerkinElmer and Thermo Fisher Scientific each raised revenue guidance.



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Combined calendar year second quarter sales for companies in the **IBO** Life Science and Analytical Instrument Sales Indexes increased 8% excluding acquisitions and currency effects. The growth rate accelerated from the same

period a year ago, as both industrial and life science end-markets exhibited healthy demand. Driving results were Bio-Rad Laboratories Life Sciences, BioTechne Protein Platforms and Illumina, which reported organic sales growth of 18.9%, 19% and 25.4%, respectively.

Although some companies, such as Agilent, Bruker, PerkinElmer and Thermo Fisher, commented on their quarterly conference call on the impact of Chinese-US tariffs, no company reported related changes in customer purchase behavior and detailed only minor operating effects. Changes these companies have started or planned in reaction to the tariffs include relocation of manufacturing outside of China, revised supply chains and possible price increases.

End-markets

Pharmaceutical and chemical markets led growth for companies in the *IBO* Sales Indexes. PerkinElmer and Thermo Fisher both reported double-digit growth for the pharmaceutical market for total company sales. Waters and Shimadzu AMI reported a bounce back in Indian pharmaceutical sales from the first quarter.

Industrial market sales growth was also healthy, led by chemical and associated end-markets. Highlights included double-digit growth for Agilent Technologies' chemical and energy sales, fine chemicals for Spectris Materials Analysis and Waters' TA segment, as well as high single digits for PerkinElmer DAS's industrial sales. Bruker Scientific Instruments (BSI) and Shimadzu Analytical & Measuring Instruments (AMI) reported strong sales for materials analysis applications.

Academic and government sales also increased. Waters, in particular, reported strong growth in this market, while Thermo Fisher Scientific's academic and government sales were up high single digits. However, for other companies, such as Agilent Technologies and QIAGEN, growth was more subdued.

Sales to the applied markets for *IBO* Sales Index companies were mixed. Agilent and Shimadzu AMI noted slower sales in China due to the reorganization of government ministries. Nonetheless, environmental markets were particularly strong for Hach and Shimadzu AMI, led by China.

Geographic markets

All major regions showed growth for *Index* companies in the calendar year second quarter. Unaffected by macroeconomic concerns, Chinese sales were particularly strong. Agilent, BioTechne, Illumina, QIAGEN, Thermo Fisher and Waters each reported double digit revenue growth in the country and remained optimistic about sales this year.

In fact, for Asia overall, sales for life science product lines were especially strong. Including China, Illumina sales in the region grew 32%, Bio-Techne sales rose in the mid-teens and Merck Life Science's Asian revenues were up nearly 14% in constant currency. However, QIAGEN sales to the region grew just 1%. Additionally, Danaher Life Science and Bio-Techne reported strength in Japanese sales, a pick up from recent trends.

Americas sales growth was also healthy, up double digits for Illumina, QIAGEN and Shimadzu AMI. In contrast, Waters' US sales declined.

European sales for *Index* companies were mixed. At the high point, Shimadzu AMI sales rose 18%, but Agilent recorded flat sales due to year over year comparison. Illumina reported EMEA growth of over 30%, while Tecan's first-half sales were up 24% for the region.

Product Lines

Both instrument and consumables revenues did well for several companies, including Agilent, BSI and PerkinElmer DAS. For instruments in particular, BSI and Thermo Fisher reported good growth for MS, although Waters noted slower sales for its high-end MS systems. All three companies reported healthy LC sales. In contrast, Shimadzu



reported slower LC revenue growth due to declines in Japan and China. Both Agilent and Shimadzu noted good GC growth, assisted by petrochemical sales in China. Molecular spectroscopy system revenue growth was highlighted by Agilent as well as BSI. For life science applications, both BSI and PE reported good in vivo imaging sales growth.

Life Science Sales Index

IBO Life Science Sales Index revenues increased year over year, led by particularly strong growth from Illumina. QIAGEN Life Science and Tecan Life Science recorded low-single digit growth, noting the effect of year-over-year comparisons, while NanoString Technologies' sales declined.



Quarterly IBO Life Science Sales Index

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Index operating profit margin was flat, as a number of companies stepped up investments in new markets and product lines. Affecting the growth were notable increases for Bio-Rad Life Sciences and Illumina, driven by stronger-than-usual second quarter sales.

Analytical Sales Index

Organic sales growth for the *Index* decreased slightly from calendar year first quarter, but was up year over year. Industrial sales continued their rebound. Demand was broad based, spanning a number of technologies, including ICP-MS and LC/MS.



Quarterly IBO Analytical Instrument Sales Index



Operating margins improvement increased from a year ago, with businesses such as Spectris Materials Analysis and Thermo Fisher Scientific, focused on operational improvements. Agilent Technologies and PerkinElmer each increased operating margin by over one hundred basis points.

IBO Life Science Index: Bio-Rad Laboratories (Life Science); Biotage; Bio-Techne (Biotechnology, Protein Platforms); Fluidigm*; Illumina; Merck KGaA (Life Science)*; NanoString Technologies; Pacific Biosciences; QIAGEN (Life Sciences); Tecan (Life Sciences); Thermo Fisher Scientific (Life Science Solutions).

IBO Analytical Instrument Index: Agilent Technologies (Life Sciences and Applied Markets, Agilent Crosslab); Bruker (Scientific Instruments); HORIBA (Process and Environmental Instruments & Systems, Scientific Instruments & Systems); Oxford Instruments*; PerkinElmer (Discovery and Analytical Solutions); Shimadzu (Analytical and Measuring Instruments); Spectris (Materials Analysis)*; Thermo Fisher Scientific (Analytical Technologies); Waters*.

*Adjusted operating profit used in calculations

Tecan Acquires NGS Company

Männedorf, Switzerland 8/16/18—Tecan, which supplies lab instruments and solutions, has agreed to acquire NuGEN for \$54.5 million in cash, equivalent to around less than four times expected fiscal 2018 revenues. With more than 70 employees, NuGEN provides kits and sample preparation consumables for NGS and microarrays. "NuGEN's innovative NGS kits and genomic sample preparation solutions are an excellent complement to our industry leading automated workstations for genomic applications," commented Tecan CEO Dr. David Martyr. "Through this acquisition, we are accelerating our broad genomics strategy and further increase our recurring revenues. With further dedicated solution offerings in one of the fastest growing market segments in life sciences, we will be able to enhance the above market average growth of Tecan in years to come." NuGEN CEO Nitin Sood was named vice president and general manager of Tecan's NGS reagents business.

Asked how NuGEN's NGS sample preparation products are differentiated from competitors' offerings, a Tecan spokesperson told **IBO**, "The newly launched Celero DNA-Seq with NuQuant library system, for example, provides researchers with a simplified library preparation workflow with integrated quantification for DNA sequencing." Advantages include fewer steps, no requirement for purification and is additive only, which makes automation easier. Overall processing time is 3 hours, with a standard plate reader used for online QC. Discussing the unique automation capabilities that Tecan can deliver for this application, he said, "Together with NuGEN, Tecan can leverage its automation expertise and leading position within the market for genomic instruments to offer complete solutions for NGS library preparation, comprising dedicated workstations, accompanying consumables and differentiated NGS reagents. With Tecan's global presence, we see an opportunity to expand the business with an increased presence in North America, Europe as well as expanding sales capabilities in China—making the technology accessible to more customers."

Tecan expects to triple NuGEN's revenues by 2023 as part of the CHF 75 million (\$76 million at CHF 0.99 = \$1) in sales generated by its genomics strategy. The acquisition is anticipated to become accretive to Tecan EPS before transaction-related amoritization in 2022. The transaction is expected to close in the next few weeks.

10x Makes First Acquisition

Pleasanton, CA 8/28/18-Genomics firm 10x Genomics has acquired Epinomics for an undisclosed amount.



Epinomics' patent portfolio includes foundational IP relating to ATAC-seq (Assay for Transposase Accessible Chromatin with high-throughput sequencing). 10x Genomics plans to integrate Epinomics' technology into its Chromium Single Cell ATAC Solution launching later this year. "Today's acquisition gives us a strong team, IP and technology that has been enthusiastically validated by customers," commented 10x Genomics CEO and Co-founder Serge Saxonov. "It provides a foundation for powerful new products and positions us well to become the leader in epigenomics."

ATAC-seq is used to study the structure and composition of chromatin genome wide. Advantages include a two-step protocol, speed, less bias due to the use of no antibodies or tags, and the requirement of only 500-50,000 cells. Epigenomics provides ATAC-seq data analysis tools. Last year, the company announced a collaboration with Stanford University's Parker Institute for Cancer Immunotherapy to use biomarkers for immuno-oncology.

Bruker Further Grows Infectious Disease Diagnostics Business

Billerica, MA 8/24/18—Scientific instrument firm Bruker has agreed to acquire an 80% stake in Germany-based Hain Lifescience for an undisclosed amount. Hain Lifescience is expected to record \$38 million in revenues this year and is profitable. Hain Lifescience provides sample preparation products, and CE-IVD-marked tests for microbiology and virology infectious disease molecular diagnostics, as well as a PCR-based system utilizing a novel assay format. "Hain is a great fit for Bruker's Microbiology & Diagnostics business, which is one of the key drivers for our *Project Accelerate*. With this planned acquisition, we expect to broaden our footprint in molecular diagnostics, particularly in microbiology and virology testing solutions," stated Bruker President and CEO Frank Laukien. Hain is well-known in the fields of tuberculosis testing and other mycobacterial infection testing. The deal is expected to be accretive to 2019 non-GAAP EPS by \$0.01-\$0.02. Hain Lifescience Managing Directors David Hain and Tobias Hain will retain their titles in the joint business, which will be known as Bruker-Hain.

Dr. Wolfgang Pusch, executive vice president for Microbiology & Diagnostics at Bruker Daltonics, told **IBO**, "Hain has an existing profitable business around established PCR assays with a focus in the field of infectious disease testing. The GenoType assays allow for the detection of PCR fragments by hybridization on nitrocellulose strips. This approach is straightforward and easy to use. It can also readily be applied in developing countries with high prevalence of tuberculosis where the standard of healthcare might not be at the same level as in the USA or in Europe." He added, "In addition Hain has a very interesting innovation pipeline with an innovative real-time PCR system, the Fluorocycler XT and a proprietary assay format, the so-called Liquid Arrays which will allow for a higher level of multiplexing in the PCR assay."

Asked about possible FDA submission for Hain Lifescience's tests, Dr. Pusch said, "Typically, we pursue regulatory approval in Europe first. Over time, we intend to bring some Hain products also to the US markets, especially the upcoming innovative Liquid Array syndromic panel assays, which are currently in the R&D pipeline."

In regards to Bruker's current offerings for tuberculosis testing, he commented, "The MALDI Biotyper has broad microbial reference libraries available. A special library also covers mycobacteria, which can be used to identify the tuberculosis complex. According inactivation protocols are available. In contrast, the molecular assays from Hain do not need prior cultivation and thus enable a rapid answer directly from patient samples."

Bruker is further building upon its microbiology franchise, which is anchored by its MALDI Biotyper system, with an installed base of more than 2,700 systems. Last year the company purchased InVivo Biotech Services (see **IBO** <u>1/15/17</u>), a contract manufacturing organization, and a leading provider of monoclonal antibodies and recombinant proteins. The company has also focused on its diagnostic dbusiness with the purchases of MERLIN Diagnostika (see **IBO** <u>9/30/17</u>).



Bionano Genomics Completes IPO

San Diego, CA 8/21/18; Washington, DC 8/22/18—Life science instrument firm Bionano Genomics has completed an IPO, listing on the NASDAQ (see **IBO** 7/31/18). The company offered 3,360,000 units (each unit consists of one share and a warrant to purchase one share) at a price of \$6.125 per unit, generating gross proceeds of \$20.6 million before underwriting and offering expenses. On September 21, the common stock and warrants will begin trading separately under the respective symbols BNGO and BNGOW, respectively.

Before expenses, the company announced proceeds of \$19.1 million. The company had initially planned to offer 3.35 million shares at a price of \$8-\$10 per share. The stock closed out the month at a price of \$6.20 per share.

IBO Stock Indexes Ride Markets' Wave in August

US markets continued to show volatility in August, but nevertheless were up for the month. The Dow Jones Industrial Average and S&P 500 reached a four-year monthly high sparked by positive earnings news and US economic growth. On August 28, the US Commerce Department issued its latest revised estimates for second quarter GDP growth, increasing it from 4.1% to 4.2%. Market volatility for the month was marked by concerns about additional US-China tariffs and the decline of the Turkish lira. The Dow Jones, S&P 500 and NASDAQ finished the month up 2.2%, 3.0% and 5.7%, with both the S&P 500 and NASDAQ posting faster growth than in July.



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Laboratory Instruments and Products Stock Index

The *IBO* Laboratory Instruments and Products Stock Index rose 4.2% in August, with double-digit growth for the year. NanoString Technologies and Pacific Biosciences led all gainers, rising 38% and 31%, respectively. Four companies recorded share declines, with Luminex plunging 17%.



Company	Date Rep.	Fiscal Quarter	2018 Adj. EPS	Analyst Consensus	Es	Vs. timate	YOY Growth	2017 Adj. EPS
Laboratory	Instrume	nts and Pr	oducts Sto	ck Index				
А	14-Aug	Q3	\$0.67	\$0.63	1	\$0.04	13.6%	\$0.59
BDX	3-Aug	Q3	\$2.91	\$2.85	1	\$0.06	18.3%	\$2.46
BIO	7-Aug	Q2	\$1.64	\$1.35	1	\$0.29	182.8%	\$0.58
BRKR	2-Aug	Q2	\$0.25	\$0.25	⇔	\$0.00	8.7%	\$0.23
FLDM	2-Aug	Q2	(\$0.16)	(\$0.30)	1	\$0.14	-59.0%	(\$0.39)
KEQU	28-Aug	Q1	\$0.50	NA		NA	19.0%	\$0.42
LMNX	6-Aug	Q2	\$0.15	\$0.19	₽	-\$0.04	-25.0%	\$0.20
MTSC	6-Aug	Q3	\$0.49	\$0.63	₽	-\$0.14	-12.5%	\$0.56
NSTG	7-Aug	Q2	(\$0.80)	(\$0.71)	Ŷ	-\$0.09	300.0%	(\$0.20)
PACB	2-Aug	Q2	(\$0.17)	(\$0.17)	\$	\$0.00	-34.6%	(\$0.26)
PKI	1-Aug	Q2	\$0.91	\$0.86	1	\$0.05	35.8%	\$0.67
QTRX	8-Aug	Q2	(\$0.34)	(\$0.28)	4	-\$0.06	NA	NA
TECH	7-Aug	Q4	\$1.34	\$1.29	1	\$0.05	45.7%	\$0.92
Diversified	Laborator	y Stock In	dex					
GLW	25-Jul	Q2	\$0.38	\$0.37	1	\$0.01	-17.4%	\$0.46
TDY	2-Aug	Q2	\$2.32	\$1.66	1	\$0.66	33.3%	\$1.74

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In August, 13 of the 20 of the companies in the *Index* announced quarterly earnings results. On August 14, **Agilent Technologies** reported fiscal third quarter financials and forecast fiscal fourth quarter adjusted EPS of \$0.72-\$0.74, compared to \$0.67. The company also raised its fiscal full-year EPS guidance by \$0.05 to \$2.69-\$2.71, adjusted for updated currency effects. Incremental duty costs related to US-China tariffs are expected to cut EPS by \$0.01. Last month, **Thermo Fisher Scientific** stated that it expects a \$0.03 impact on its adjusted EPS in the second half of 2018 as a result of US-China tariffs.

After topping analysts' adjusted EPS and internal estimates on August 1, **PerkinElmer** raised its 2018 earnings guidance. The company now expects full-year adjusted EPS of \$3.65, a \$0.15 increase, which would represent a 26% rise year over year. Third quarter adjusted EPS is forecast to grow 26% to \$0.92.

In contrast, on August 7, **MTS Systems** lowered its fiscal 2018 adjusted EPS forecast to \$3.25-\$3.35 from the previous estimate of \$3.55-\$3.85 due to weakness in its ground vehicle business. The company's fiscal third quarter adjusted EPS missed analysts' estimates.

Also on August 7, **Bio-Techne** reported fiscal 2018 results. For the year, adjusted EPS increased 15% due to operational improvements, tax reform and currency. The company did not provide an adjusted EPS forecast for fiscal 2019.

As for analysts' ratings, on August 7, Morgan Stanley upgraded **Illumina** from an "underweight" rating to "equal weight." On August 8, Cantor Fitzgerald initiated coverage of **Pacific Biosciences** with a rating of "overweight."

In other news, **NanoString Technologies** announced on August 13 the results of a public offering, including writers' options, of 4.6 million shares at \$12.50 per share. Proceeds totaled \$53.9 million.

In addition, several companies announced debt offerings during the month. **Illumina** announced plans to issue \$650 million in convertible senior notes due in 2023. An additional offering of \$100 million to initial purchasers brings the total offering to \$750 million. Use of the proceeds will include the repurchase of \$150 million in common stock. Thermo Fisher announced on August 8 that it issued in a public offering €600 million (\$698 million) in floating rate senior notes due 2020. The anticipated net proceeds of approximately €597.6 million (\$695 million) after expenses will be used to pay down outstanding debt.



Diversified Laboratory Stock Index

Despite August gains for the major indexes, *IBO*'s *Diversified Laboratory Stock Index* declined 0.4% for the month. Over half of the *Index*'s stocks showed declines, led by **Illinois Tool Works**. **Teledyne Technologies** recorded the largest jump by far.

The increase comes in wake of **Teledyne Technologies'** announcement of record earnings on August 2. Raising its full-year GAAP EPS, the company now expects new range of \$8.18-\$8.28, up from \$7.67-\$7.77. Third quarter GAAP EPS is estimated to be \$2.01-\$2.06 compared to \$1.90.

Roper Technologies announced on August 14 the pricing of a \$700 million in public offerings of senior notes due 2023 and \$800 million in senior notes due 2028. The company expects to use the proceeds to repay outstanding notes and a credit facility, as well as to fund general corporate purposes.

International Stock Indexes

Major Asian indexes ended the month mixed. China's Shanghai SE Composite was down -0.55% due to trade concerns, Hong Kong's Hang Seng Index fell 0.98%. But Japan's Nikkei 225 was up 1.5% and South Korea's KOSPI Index rose 1.54%.

Asia Pacific companies in the *IBO* Stock Table were mixed. **GL Sciences** rose 8.9%, while **Precision System Science** declined 11.1%. On August 7, **Shimadzu** announced fiscal 2019 first quarter results of ¥14.77 (\$0.14) EPS, up 79.2%, in part due to currency effects. For fiscal 2019, the company forecasts EPS of ¥108.63 (\$1.00) for a 7.3% increase. **HORIBA** reported first half results on August 3, with a double-digit percentage increase in revenue, operating profit and net income. However, the company lowered its full-year sales forecast.

In Europe, major stock indexes were depressed in August. The UK's FTSE 100 declined 3.0%, while Germany's DAX fell 2.0% and France's CAC was down 0.91%. European shares in the *IBO Stock Table* were mixed in August, with **Datacolor** and **Tecan** falling. **Tecan** reported first-half financial results on August 16. Diluted EPS increased 10.8% to CHF 2.46 (\$2.48) as the company's Partnering Business posted strong sales (see <u>Bottom Line</u>). **Merck KGaA** announced second quarter results on August 9, posting an adjusted EPS that declined 18.5% to €1.23 (\$1.46) impacted in part by negative currency effects.

All UK shares in the *IBO Stock Table* were up this month with the exception of **Scientific Digital Imaging**. Nonetheless, the company is up 71% for the year. **Horizon Discovery** led all companies, gaining 16.7%. In mid-August, Peel Hunt upgraded **Spectris** to an "add" rating, but Shore Capital downgraded the stock to "hold". During the month, Spectris completed a £100 million (\$137 million) stock buyback.



	Market Value	52-Wee	k Range	Price	Change	Change	P/E	EPS
Company: Exchange	(USM)	Low (\$)	High (\$)	8/31/18	1 Month	YTD	(ttm)	(ttm)
Laboratory Instruments and Produ								
Agilent Technologies: n	\$21,610	60.42	75.00	\$67.54	2.3%	0.9%	25	2.65
Becton, Dickinson and Company: n	\$69,972	191.53	262.67	\$261.87	4.6%	22.3%	25	10.44
Bio-Rad Laboratories: n	\$8,035	212.02	345.15	\$325.30	6.1%	36.3%	62	5.22
Bio-Techne: o	\$7,221	119.01	194.31	\$192.17	19.6%	48.3%	43	4.47
Bruker: o	\$5,707	28.13	36.53	\$35.58	9.8%	3.7%	28	1.29
Enzo Biochem: n	\$179	3.95	11.50	\$4.59	3.8%	-43.7%	NM	-0.09
Fluidigm: o	\$232	4.43	8.38	\$7.92	23.8%	34.5%	NM	-0.91
Harvard Bioscience: o	\$205	2.95	6.70	\$5.70	0.0%	72.7%	32	0.18
Illumina: o	\$52,160	196.00	357.93	\$354.83	9.4%	62.4%	65	5.43
Kewaunee Scientific: o	\$87	24.56	38.80	\$31.90	0.9%	10.0%	14	2.35
Luminex: o								
Mettler-Toledo: n	\$1,254	18.62	35.37	\$28.21	-16.7%	43.2%	16	1.79
	\$14,841	540.24	697.26	\$584.46	-1.4%	-5.7%	31	18.72
MTS Systems: o	\$965	42.00	57.50	\$54.10	-0.8%	0.7%	30	1.79
NanoString Technologies: o	\$416	5.87	16.75	\$16.17	37.9%	116.5%	NM	-2.34
Pacific Biosciences: o	\$658	2.02	5.70	\$4.99	31.3%	89.0%	NM	-0.74
PerkinElmer: n	\$10,226	66.48	93.15	\$92.43	16.7%	26.4%	29	3.24
QIAGEN: 0	\$8,829	30.20	39.45	\$38.97	7.9%	26.0%	29	1.34
Quanterix: o	\$418	13.00	24.81	\$16.73	11.6%	-14.4%	NM	-8.30
Thermo Fisher Scientific: n	\$96,195	181.51	240.88	\$239.10	1.9%	25.9%	23	10.35
Waters: n	\$14,844	177.58	220.20	\$189.48	-3.9%	-1.9%	24	7.82
Diversified Laboratory								
AMETEK: n	\$17,822	62.82	79.32	\$76.96	-1.1%	6.2%	26	2.97
Corning: o	\$27,825	26.11	35.10	\$33.51	1.0%	4.8%	21	1.61
Danaher: n	\$72,453	82.68	106.08	\$103.54	0.9%	11.5%	24	4.33
Honeywell	\$118,120	136.17	165.13	\$159.06	-0.4%	3.7%	21	7.67
Ilinois Tool Works: n	\$47,047	134.66	179.07	\$138.88	-3.1%	-16.8%	19	7.28
Roper Technologies: n	\$30,780	227.46	312.38	\$298.37	-1.2%	15.2%	28	10.56
Teledyne Technologies: n	\$8,485	147.43	238.78	\$237.26	8.1%	31.0%	30	8.00
Xylem: n	\$13,658	61.54	79.83	\$75.91	-0.8%	11.3%	29	2.65
Laboratory Instruments and Produ	ucts			\$414.70	4.2%	22.9%	32	
Diversified Laboratory				\$278.37	-0.4%	2.4%	25	
Dow Jones Industrial Average				25,964.82	2.2%	5.0%		
S&P 500				2,901.52	3.0%	8.5%		
NASDAQ Composite				8,109.54	5.7%	17.5%		
Region	Market Value	52-Wee	k Range	Price	Change	Change	P/E	EPS
Company	(Local M)	Low (L)	High (L)	8/31/18	1 Month	YTD	(ttm)	(ttm)
Pacific Shares	(Local III)	204 (2)	ingi (L)	0/51/10	1 month	110	(um)	(ttill)
GL Sciences: t	¥18,340	1,211	2,345	¥1,639	8.9%	-23.6%	11	¥144.19
					-4.3%	-23.0%	15	¥288.98
Hitachi High-Technologies: t	¥601,235	3,795	5,680	¥4,365				
HORIBA: t	¥301,963	6,170	9,590	¥7,100	-7.7%	4.6%	20	¥361.68
JEOL: t	¥112,867	488	1,240	¥1,155	4.0%	80.8%	162	¥7.14
Precision System Science: os	¥9,805	403	791	¥425	-11.1%	-35.7%	NA	-¥26.32
Shimadzu: t	¥951,865	1,988	3,430	¥3,215	1.1%	25.5%	37	¥87.56
Techcomp: hk	HKD 898	1.25	4.19	¥3	0.9%	82.1%	42	HKD 0.01
European Shares (London)		27.2221					102511	1000000
Abcam: I	£3,108	9.47	16.44	£15.16	2.6%	43.7%	31	£0.49
Halma: I	£5,436	10.64	14.70	£14.32	1.8%	13.7%	43	£0.34
Horizon Discovery: I	£304	1.28	2.66	£2.17	16.7%	-9.6%	NA	-£0.14
Oxford Instruments: I	£556	6.76	11.74	£9.69	1.6%	13.9%	NA	-£0.44
Scientific Digital Imaging: I	£38	0.12	0.47	£0.42	-4.5%	70.5%	17	£0.02
Spectris: I	£2,775	22.21	29.57	£23.54	2.8%	-5.3%	96	£0.24
European Shares (Other)								
Biotage: st	SEK 8,373	56.00	132.20	SEK 129.40	17.0%	54.0%	52	SEK 2.5
Datacolor: s	CHF 136,112	732.00	900.00	CHF 810.00	-4.1%	-3.6%	20	CHF 40.1
Marak KCallin	€11,696	75.26	100.37	€ 90.50	2.8%	0.8%	24	€ 3.84
Merck KGaA: g								
Sartorius: g	€ 5,092	68.14	140.50	€ 136.00	9.2%	80.3%	61	€2.23

The *IBO* Stock Indexes are weighted by marked capitalization. The Indexes' averages for the financial ratios presented are also weighted statistically to reflect the relative sizes of the constituent companies. Laboratory Instruments and Products Index: 12/30/11 = 100. Diversified Laboratory Index: 12/30/11 = 100. Exchanges: n = NYSE; o = NASDAQ; t = Tokyo; hk = Hong Kong; l = London; g = Germany; s = Switzerland; st = Sweden; no = Nordic Market; os = Osaka Securities. N/A = not available; NM = not meaningful.

Second Quarter Results: Agilent Technologies, Bruker,



Danaher, Merck KGaA and Shimadzu

Chemical End-markets Drive Agilent Growth

Agilent Technologies' fiscal 2018 third quarter revenues included 1.6% growth and 0.5% growth from currency and acquisitions, respectively (see <u>IBO 8/15/18</u>). Consumables, services and informatics accounted for 58% of sales.

Agilent Technologies Q3 FY18							
	Rev. (M)	Chg.	Organic Chg.	% of Rev.			
Total	\$1,203	8.0%	5.9%				
Life Sciences & Applied Markets	\$540	5.9%	5%	45%			
Agilent CrossLab	\$426	10.4%	8%	35%			
Diagnostics & Genomics	\$237	8.7%	5%	18%			

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Agilent Techologies Q3 FY18						
	Op. Margin	Chg. (bps)				
Total	22.4%	118				
Life Sciences & Applied Markets	22.9%	150				
Agilent CrossLab	23.8%	40				
Diagnostics & Genomics	18.5%	140				

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By end-market, chemical and energy sales grew the fastest, up 12% to make up 25% of company sales. End-market growth was led by the division's chemicals segment, which also includes semiconductor and materials testing sales.

Pharmaceutical and biotech sales rose 8% to account for 30% of company sales, with growth for both biopharma and small molecule end-markets. Product lines showing strength included MS, cell analysis, CrossLab and genomics.

Diagnostics and clinical sales increased 5% and included double-digit revenue growth for the genomics businesses as well as increased revenue for the reagent partnership business. However, the company reported weakness in the pain management market and the Nucleic Acid Solutions Division business, for which sales declined.

Sales to academic and government customers increased 3%, with double-digit growth in China and the rest of Asia. This market accounted for 8% of company revenues.

Sales to the food end-market fell 1%, with sales to Europe declining as a result of a tough annual comparison. Food sales in China also declined due to the ongoing reorganization of ministries. These changes to the ministries also affected Environmental and forensics sales, which were flat for the company as a whole.

Despite slowing sales in these Chinese markets, China sales for Agilent in total jumped 12.1% to make up close to 60% of Asia-Pacific sales. Chinese sales grew double digits for the chemicals and energy, and pharma markets, as well as for Diagnostics and Genomics, and Cross Lab.

Agilent Technologies Q3 FY18					
	Chg.	% of Rev.			
Americas	8.0%	34%			
Europe	3.7%	28%			
Asia Pacific	10.2%	38%			
China and Hong Kong	12.1%	22%			

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Life Sciences and Applied Markets Group revenue growth was led by LC/MS, cell analysis and IPC-MS sales. Sales of the Agilent CrossLab Group included mid-teens growth in China. The company also reported in the quarter that over half of consumables sales were digital for the first time.



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Agilent increased its fiscal 2018 core revenue guidance by \$10 million to 6.1% organic growth. Fiscal fourth quarter revenues are expected to total \$1.24-\$1.26 billion, compared to \$1.19 billion in the same period a year ago.

Bruker BSI Sales Increase Double Digits

Second quarter Bruker Scientific Instrument (BSI) sales increased to make up over 90% of company revenues. (See <u>IBO 8/15/18</u>.) BSI Systems sales grew 10.3% to account for 71% of BSI revenues, while Aftermarket sales jumped 12.7%.

Bruker Q2 2018							
	Rev. (M)	Chg.	Currency	Acq./Div.	Organic Chg.		
Total	\$443.7	6.9%	3.3%	0.7%	2.9%		
Bruker Scientific Instruments	\$402.4	11.0%	7.8%	3.2%	7.1%		

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Bruker Q2 2018					
Adj. Op. Profit	Chg.	Adj. Op. Margin	Chg. (bps)		
\$58.9	10.1%	13.3%	40		

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All three BSI units reported revenue growth. In the first half, BioSpin sales rose in the low single digits, with particularly strong growth for NMR sales for clinical and phenomic applications. Rebounding from last year, preclinical imaging sales showed positive growth, especially PET/SPECT systems.

First-half sales for CALID grew mid-single digits. MS sales increased as microbiology and life science system revenues were higher. Within CALID, Optics sales also grew, but Detection sales declined.

First-half Nano sales increased high single digits as industrial demand remained strong.. Highlights included sales to industrial and academic research, and semiconductor metrology end-markets. AXS revenue increased due to industrial materials-research applications.



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By region, both European and Asia Pacific BSI sales rose low double digits. In the Americas, BSI sales rose midsingle digits.





Bruker updated its 2018 revenue guidance from 7% to 6.5% growth, including 3.5% organic growth, up from a previous estimate of 3%. Currency is expected to reduce growth by 2%, while acquisitions will add 1% growth.

Danaher Life Sciences Leads Segments' Growth

Core Danaher revenues rose 6% for the second quarter. (See **IBO** 7/31/18.) The Life Sciences, and Environmental and Applied Solutions led all divisions' growth, with sales for both up double digits.

Selected Danaher Segments Q2 2018							
	Rev. (M)	Chg.	Currency	Acq./Div.	Organic Chg.		
Life Sciences	\$1,605.2	16.0%	2.5%	6.0%	7.5%		
Environmental & Applied Solutions	\$1,091.5	11.0%	-2.5%	-1.5%	7.0%		

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Selected Danaher Segments Q2 2018						
	Op. Margin	Chg. (bps)	Core Chg. (bps)			
Life Sciences	18.2%	220	290			
Environmental & Applied Solutions	23.0%	-90	-50			

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Within the Life Sciences segment, Leica Microsystems revenue rose low double digits and SCIEX revenue grew high single digits. Sales for Pall increased mid-single digits, including double-digit growth for biopharmaceutical sales. In addition, the company reported solid growth for Beckman Coulter Life Sciences, citing new product sales. Japanese sales for Life Sciences were also strong.

Danaher Life Science Rev. Q2 2018



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Within the Environmental and Applied Solutions segment, water quality sales grew high single digits, including a double-digit increase for Hach sales. Hach reported good sales in industrial as well as municipal markets.



Danaher Env. & Applied Solutions Rev. Q2 2018

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Danaher forecasts third quarter core revenues to increase 4%-4.5%. Full-year core revenues are expected to rise mid-single digits.

Bioprocess Sales Drive Merck KGaA Life Science

Merck KGaA Life Science represented 41% of total company sales in the second quarter, reporting the fastest growth rate among the company's three business segments. (See $\underline{IBO} 8/15/18$.)

Merck KGaA Life Science Q2 2018						
	Rev. (M)	Chg.	Currency	Organic Growth	% of Rev.	
Total	€ 1,543	3.2%	-4.6%	7.7%		
Process Solutions	€ 612.0	7.9%	-4.6%	12.5%	40%	
Research Solutions	€ 517.0	-0.2%	-4.5%	4.1%	34%	
Applied Solutions	€ 414.0	1.0%	-4.7%	5.7%	27%	

Click to enlarge

Merck KGaA Life Science Q2 2018						
Adj. Op. Profit (M)	Chg.	Adj. Op. Margin	Chg. (bps)			
€ 452	-0.4%	29.3%	107			

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Within the Life Science unit, Process Solutions posted the fastest growth rate, driven by the bioprocessing business' sales in Asia-Pacific and North America. Product line highlights were single-use, downstream and cell culture media products. Sales of Research Solutions were led by sales of life science reagents and kits, and sales in North America and Europe. In the Applied Solutions business, revenue increases were led by Advanced Analytical and lab water segment revenue, as well as sales in North America and Asia-Pacific.

Merck KGaA Life Science Q2 2018						
	Chg.	Currency	Org. Growth	% of Rev		
Europe	4.3%	-1.1%	5.4%	35%		
North America	-0.4%	-6.7%	6.4%	35%		
Asia Pacific	9.6%	-4.4%	13.9%	25%		
Latin America	-7.0%	-14.8%	7.5%	4%		
Middle East & Africa	-4.3%	-2.1%	-2.9%	1%		

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The company forecast Life Science sales to grow 5%-6% on an organic basis for 2018, compared to a previous forecast of 4% organic growth.



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Shimadzu AMI Sales Led by the Americas

Shimadzu Analytical & Measuring Instruments' (AMI) first quarter fiscal 2019 sales rose 12.0% to make up 60% of total company revenues. (See <u>IBO 8/15/18</u>.) AMI orders grew 5.7%, led by an 11.3% increase in India and 8.2% growth in China.

Shimadzu AMI Q1 FY19				
	Rev. (B)	% Chg.		
Total	¥51.6	12.2%		
Key Models	¥27.4	24%		
Other	¥24.4	12%		

Click to enlarge

Shimadzu AMI Q1 FY19					
Op. Profit	Chg.	Local Currency Chg.	Op. Margin	Chg. (bps)	
¥5.7	10.3%	21.8%	11.0%	850	

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By product line, revenue growth was led by sales of environmental measurement instruments, including water

quality products, in China. LC and MS sales showed strength in North America and Europe, in particular LC sales to pharmaceutical and CRO customers. However, LC and MS sales declined in Japan and China. As for GC, sales rose outside of Japan and were especially strong in China related to petrochemical sales.

Shimadzu AMI Q1 FY19				
	Rev. (B)	% Chg.		
Total	¥51.6	12.2%		
Key Models	¥27.4	24%		
Other	¥24.4	12%		

Click to enlarge

By end-market, CRO revenue increased. In the materials/machinery/electrical/automotive market, sales to the materials field for regulatory compliance were especially strong. In Japan, sales to the academic market were a highlight.

Sales outside of Japan represented 63% of AMI revenue. Geographically, North American sales rose 17.1% in local currency to \$5.5 billion (\$50.4 million = \$109.08 = \$1). South American sales rose 20.1% in local currency to \$0.9 billion (\$82.3 million).

Shimadzu AMI Q1 FY19					
-	% of Rev.	Chg.	Local Currency Chg		
Japan	37%	14.7%	14.7%		
Americas	12%	15.7%	17.1%		
Europe	11%	18.0%	11.3%		
China	26%	18.0%	10.2%		
Other Asian	11%	7.6%	9.1%		
Other	3%	-4.7%	-3.4%		

Click to enlarge

For fiscal 2019, the sales growth forecast remains the same with a 9.4% increase bolstered by changes in currency effects.

Lateral Flow Assays

Lateral flow assays are the most widespread diagnostics tool used outside the laboratory. The technology behind this ubiquitous tool is an immunoassay that operates on a paper strip, enabling the detection and quantification of analytes in complex mixtures.

Typically, this rapid test consists of overlapping membranes: a sample pad where the sample is applied; a reagent pad containing antibodies targeting the specific analyte; a reaction or detection zone where anti-target analyte antibodies are displayed in a line, acting as a capture zone; and a waste-reservoir absorbent pad that guides the sample by capillary action.

The assays work when a liquid sample containing the analyte of interest is applied to one end of the strip and moves through it by capillary force. The antibodies attached to the pad interact with the analyte when it pasess by. These antibodies are typically conjugated to colored particles (generally latex microspheres or colloidal gold). The target analyte bonded to the conjugated antibody migrates along the strip until reaching the reaction zone, where anti-target analyte antibodies react with the analyte bound to the conjugated antibody. This results in a colored line. A second colored line is often present as a control, indicating the proper liquid flow through the strip.

Some of the advantages of this method include its long shelf life, lack of refrigeration requirements, ease of use, inexpensive production cost, and the fact that it is widely accepted by users and well-known by regulatory authorities. The latter constitutes an essential part of its success, as typically new diagnostic techniques require hundreds of millions of dollars in investment and a relatively long period of time to obtain regulatory approval.

As lateral flow assays can easily be transported to remote sites and ambulatory care settings, they are a practical alternative for point-of-care diagnostics. This branch of the diagnostics market is growing at a rapid rate, as it allows detection on site of a disease outbreak or food poisoning, among many other applications. As strips are extremely versatile and analytes can be anything from blood proteins to mycotoxins or viral particles, this technology can be applied to almost any industry. The most common markets are clinical settings, agricultural, food, biodefense, environmental and veterinary.

With initiatives focusing on precision medicine, the US is the largest market. Demand for lateral flow assays will continue to grow at a fast pace in this region. Large investments in hospitals and health care in Europe and North America will drive the sales growth of lateral flow testing in those markets, while food safety initiatives in Asia will also help boost market size.

Leading Vendors:

- Abbott
- Roche
- Becton, Dickinson

Largest Markets:

- Clinical testing
- Agriculture and Food
- Environmental

Assay Cost:

• \$1-\$100

R&D

According to new data from the NSF, between fiscal years 2016 and 2017, federal R&D obligations grew 2.8% to \$118.3 billion. The NSF defines federal obligations as representing "the amounts for orders placed, contracts awarded, services received, and similar transactions during a given period, regardless of when the funds were appropriated and when future payments of money are required." This includes funds from direct appropriations, trust funds, special accounts, fees and charges, and other federal sources, and comprise the total R&D cost, including specific project and overhead costs.

Obligations for R&D plant rose 23.6% to \$3.0 billion during fiscal 2017, while total obligation funding for research decreased 0.3% to \$66.5 billion. Basic research nominally increased 0.1% to \$32.3 billion, while applied research obligations nominally decreased 0.8% to \$34.2 billion and experimental development obligations jumped 7.2% to 51.8 billion.

Of all federal R&D obligations in 2017, 25% were research obligations, with HHS representing 48% of federal research obligations at \$32.2 billion. The DoE comprised 15%, or \$9.9 billion of federal research obligations, followed by the DoD at 11.3%, or \$7.5 billion. The NSF itself made up 9%, or \$5.7 billion of federal research obligations, while the USDA represented 3% at \$2.3 billion.

By field, life sciences accounted for 48% of total federal research obligations, followed by engineering at 19% and

physical sciences at 9%. Other sciences comprised 7% of federal obligations and environmental sciences represented 6%.

Source: <u>NSF</u>

Government

Earlier this month, the US EPA unveiled its plan to roll back the limits on greenhouse gas emissions from power plants, which will give states more control over setting the limits for carbon dioxide regulation. According to the proposal, a new plan, entitled the Affordable Clean Energy (ACE) rule, will replace the Clean Power Plan (CPP), which was established in fall 2015.

The EPA stated that its repeal of the CPP was because the Best System of Emission Reduction (BSER) of the CPP "exceeded the EPA's authority" by applying measures to the power sector as a whole instead of to individual facilities. The proposal stated that as per the EPA's statutory authority, BSER is to be "applicable to, at and on the premises of the facility for an affected source."

The proposal stated that coal-fired power plants can reduce their carbon dioxide emissions by making efficiency upgrades, which limit the amount of carbon dioxide that is emitted per unit of electricity generated. Certain technologies would contribute to these efficiency upgrades, according to the EPA, which listed the following "candidate" technologies: neural network/intelligent sootblowers; boiler feed pumps; air heater and duct leakage control; variable frequency drives; blade path upgrade (steam turbine); redesigning/replacing economizers; and improved operations and maintenance practices. It is up to states to determine which of these technologies will be applicable and appropriate at each power plant, and to establish their own levels of greenhouse emission reduction from their application.

The EPA claims that in certain situation the ACE rule will save up to \$6.4 billion compared to the CPP. Nearly 600 coal-fired electric generating units at 300 facilities may be covered by the ACE rule. The EPA is accepting comments regarding the ACE proposal for 60 days.

Biotechnology

Over the past 7 months, 38 biotechnology companies have filed for IPOs, and with several more biotech companies filing IPOs in early August, the total 2018 number is closer to 48. In contrast, 21 biotech companies filed for IPOs during the first 7 months of 2017, indicating an 81% increase in IPOs from biotech companies this year.

According to experts, biotech company activities have grown more rapidly than the general IPO market in 2018, representing approximately 33% of all IPOs. This is due to the current market that is friendly to IPOs, which affords biotech companies the opportunity to establish complete platforms for drug development. In a closed, less hospitable market, biotech companies do not have time to grow their valuations, instead usually developing one product and being acquired by big pharma companies. In these cases, the biotech companies' valuations and private investors' returns both tend to be lower. Because of this, biotech companies are moving fast to capitalize on the open IPO market before any changes due to factors such as politics and US FDA policies that may affect the approval process of drugs.

While investors in biotech companies are also interested in benefitting from the IPO-heavy market, the issue lies in deciding which biotech companies to invest in. Generally, it is suggested to focus on companies that can provide clinical study results, which not all biotech companies have, as that will those that provide information on how close the company is to getting their investigational drug application being approved.

Source: <u>Investor's Business Daily</u>



EU

According to a European Commission study that examined Scopus data between 2009 and 2016 for open access publications, Switzerland leads the EU, with 39% of its research publicly accessible. Open access is defined as freely accessible scientific research that creates opportunities for reutilizing publications, codes and data to increase scientific productivity and discoveries, while decreasing scientific misconduct.

The EU defines two types of open access: green open access refers to when an author or representative archives the scientific article in an online repository prior to, simultaneously or after publication; gold open access refers to when an article is immediately published as an open access article. While green open access publications remained the majority, their numbers decreased by two percentage points in 2016 to represent 14% of publications, while the number of gold open access publications increased one percentage point the same year to make up 14%. According to the methodology report, transitioning to open access has been sluggish due to factors including costs and journal policies. However, the study stated that the number of open access publications has been slowly growing over the past seven years.

Croatia and Estonia rounded out the top 3 European countries for open access publications, with 38% and 37% of their research available in open access format, respectively. By field, 66% of open access publications were multidisciplinary, with agriculture, forestry and fisheries, and biological science and basic medical research representing 42%, 39% and 38%, respectively.

Source: European Commission

Russia

In a survey of 52 Russian and foreign generic and original drug manufacturers operating in Russia and internationally, including distributors of pharmaceuticals, data indicated that while the Russian pharmaceutical market is on the rise, there is a simultaneous decrease of growth in production. Digitalization, online drug stores, electronic patient documents, telehealth and other factors are influencing Russian pharma companies to focus more on modernized strategies to find their footing in the changing market landscape.

In 2017, the Russian pharmaceutical market as a whole grew 7.9% in ruble terms and 24% in US dollar terms, due to a stronger average weighted ruble/US dollar exchange rate. Russian pharmaceutical output rose 3.2% to RUB 295 billion (\$4.4 billion), ranking it 14th globally in terms of pharmaceutical market size. Imports also increased 21.6% in 2017, while exports grew 14.6%. Nearly 80% of imports were from Europe, specifically Germany at 21%, France at 9% and Italy at 6%.

Patients continued a trend of purchasing less expensive generic drugs, which accounted for 65% of sales, with locally produced drugs representing 72% of those sales. Total public and private investments in the industry were more than RUB 150 billion (\$2.2 billion).

According to half of survey respondents, substantial changes in the market are not likely in 2018. Sixty percent of respondents expect revenues to expand in 2018 at an average growth rate of 10%, while 48% of respondents predict operating costs will increase 7%. Approximately one third of companies surveyed forecast a 10% rise in capital expenditure in 2018, and 27% plan to boost their staff by an average of 8%.

Source: <u>Deloitte</u>

China

Earlier this year, the General Office of the State Council of China released new "Measures for the Administration of



Scientific Data" in order to optimize the policies and processes of collecting, storing, securing and sharing data. The draft defines "scientific data" as including data that are generated through applied research, basic research and pilot tests, as well as raw data derived from monitoring, investigating and testing for the purpose of research.

The draft regulation indicates that any scientific data within the country be submitted to the "lead program entity," which is not yet established, for approval before publication. The data will be able to be shared with international collaborators, save in cases involving "state secrets," in which a special form of approval will be required from the science and technology ministry. Furthermore, the draft states that before scientific data intended for publication can be released outside of China, it must first undergo a review process by authorities.

While many experts agree that China needs improved data security and sharing policies, the draft regulation is causing concern that the new regulation provides Chinese authorities with too much power in regards to controlling the collection and output of scientific data in the country. International collaborations may also become compromised with the increase of red tape surrounding data sharing.

Source: University World News

Sequencing

Company Announcements

In July, the <u>Wall Street Journal</u> reported that the **US Department of Commerce** has decided not to pursue a request from two US senators to investigate the sale of DNA sequencers by **Thermo Fisher Scientific** to the **Chinese Ministry of Public Security**, stating that the sales were not in violation of US licensing regulations preventing sales of "surveillance and crime control" instruments to non-American allies.

In August, AI firm **Bioz** partnered with **Covaris**. Using Bioz software, Covaris will display relevant citations on its product pages.

HTG Molecular Diagnostics completed in August a masters agreement with **Oncologie** to develop biomarkers for Oncologie's immuno-oncology pipeline.

In August, **HTG Molecular Diagnostics** named Michelle Griffin, founder of **Pacific Biotechnology Consulting**, to its Board.

BC Platforms partnered with Finnish genetic technology company **Negen** in August. Negen will use BC Platforms' solution to provide detailed insights into raw genomic data for clinical reporting capabilities, including the rapid integration of Negen's genetic risk scoring tools.

BC Platforms partnered in August with **Proteus Genomics**, a clinical reference lab specializing in pharmacogenomics.

In August, **BGI** signed a memo of understanding with **Xing Technologies** to optimize DNA nanoball sequencing technology, CTC technology and point-of-care products.

BGI announced in August a cooperation agreement with Thailand's **Chulabhorn Royal Academy** and **Eastern Economic Corridor office** to work together to establish a precision medicine national platform in Thailand's eastern economic corridor.

In August, the **China National Drug Administration** cleared the first **Illumina** instrument, the MiSeq Dx Sequencing System, allowing sale of the system to hospitals and other medical institutions for IVD testing.

Blockchain firm **Nebula Genomics** announced in August that it has raised \$4.3 million in seed financing. The company also announced a partnership with **Veritas Genetics** to connect the Nebula marketplace to Veritas' Arvados open-source software platform.



Product Introductions

In August, **Oxford Gene Technology** launched an update to its SureSeq Interpret software, which is included with purchases of SureSeq NGS panels. The update features comprehensive filtering framework enabling analysis workflows to be standardized, and allows variant filtering to be overlaid to meet analytical criteria.

NRGene released in August a comprehensive soy genome diversity haplotype database based on results from its GenoMAGIC platform. The database contains de novo assemblies and all-to-all comparison of 34 varieties of soybeans.

NuGEN Technologies introduced in August a new mRNA-Seq library preparation kit integrated with the NuQuant library quantification method. The NuQuant method eliminates the need to serially dilute libraries and estimate library size.

In August, **Swift Biosciences** announced early access availability of the Swift Amplicon HS Panels, a new targeted amplicon library preparation kit for NGS of liquid biopsy samples.

Process Analysis

Company Announcements

Servomex, a Spectris company, appointed Trevor Sands as president in March, replacing Chuck Hurley.

Galvanic Applied Sciences named Rene Aldana as CEO in June. He previously served as COO of ZCL Composites.

In July, **Orbital Gas Systems** signed a memo of understanding with **SAMSON AKTIENGESELLSCHAFT** for sales and distribution of Orbital's GasPT, VE Technology and combined GasPTi analyzer.

Product Introductions

ECD Analytical in May released the Model LQ800 Multi-Channel Controller, designed to operate with 8 digital analytical and process sensors.

In June, **IONICON** launched an API for its ioniTOF, a modular, entry-level TOF MS. The setup can consist of 1 or 2 interconnected APi-TOFs used in parallel for simultaneous measurement of positive and negative polarity.

In July, **Hellma** launched a new online configurator for optical immersion probes and process flow cells that are used with fiber optic-coupled lab and process spectrometers. Features include a redeveloped user-interface and integration of the Hellma Axiom product range.

In August, **Metrohm Process Analytics** debuted the new 2029 process photometer, an integrated solution for 24/7 online analysis of critical chemical parameters in industrial processes and wastewater streams. It is available in several application-specific configurations for monitoring up to two process streams.

Bioprocess Analysis



Company Announcements

In June, **Sartorius Stedim Biotech** (SSB) signed a long-term cooperation agreement with **Siemens**. SSB will preferably use Siemens automation technologies. The automation technologies will include Siemens' industrial PCs, the S7-1500 software controller, the TIA Portal and the SCADA system Simatic WinCC, among others. As a result, SSB's product portfolio will feature a globally standardized automation platform, and SSB will introduce a new, configurable automation system for its range of systems. This agreement builds upon a previous partnership.

In June, publicly held **Entegris**, a supplier of specialty chemicals and advanced materials solutions for the microelectronics industry, acquired **Flex Concepts** for an undisclosed amount. Flex Concepts sells bioprocessing single-use bags and fluid-transfer solutions.

In July, **Pluristem Therapeutics** entered into a strategic collaboration with **Thermo Fisher Scientific**, combining Pluristem's expertise in cell therapy manufacturing, clinical development and QC with Thermo Fisher's experience in cell therapy development and bioproduction scaleup.

In August, the Swedish government and **GE Healthcare** opened the 27,000 ft² (2,500 m²) Testa Center in Uppsala, Sweden. The Center houses four bioprocessing labs for testing new discoveries for the production of biopharmaceuticals. Cell culture matrices firm **BioLamina** is the first company to run a project at the Center. Sweden invested \notin 10 million (\$11 million) in the Center and GE invested \notin 4.5 million (\$5 million).

Product Introductions

In August, **C-CIT Sensors** launched the *MeMo* affordable and easy-to-handle single-use wireless bi-parametric metabolic monitoring system for the continuous online/real-time measurement of glucose and lactate in cell cultures. The electrochemical, enzyme-based sensor can be used in defined cell culture media or blood.

MS & LC/MS

Company Announcements

In June, **Bio-Rad Laboratories** and **Bruker** entered into a comarketing agreement for their respective RAPID chromogenic media and MALDI Biotyper system, delivering a complete workflow for foodborne pathogen detection and confirmation.

Syft Technologies reported a 32% increase in unit sales of its SIFT-MS to 37 in 2017.

In July, **908 Devices** entered into a joint innovation partnership with **Hangzhou Just Biotherapeutics** (HJB) for its ZipChip platform, which is now available in China. HJB is an integrated design company focused on technologies that will accelerate development of biotherapeutics and reduce manufacturing costs.

Agena Bioscience in July named **Zhejiang Dian Diagnostics**, an independent medical lab provider, as a partner for China.

In July, **Agena Bioscience** announced it was selected to participate in the **CANCER-ID Consortium**. Agena's MassARRAY System will support mutation detection from liquid biopsy samples as part of the Consortium's work packages in lung cancer and breast cancer. The goal of the Consortium is to establish standard protocols for and the clinical validation of the use of blood-based biomarkers for cancer.

In August, **Agena Bioscience** entered into an agreement to incorporate **PerkinElmer**'s LabChip GX Touch in the upfront workflow of its MassARRAY System, targeting ctDNA in oncology liquid biopsy.

For the six months ending June 20, Proteome Sciences reported a 9.4% increase in TMT reagent and royalties



sales to £1.05 million (\$1.4 million).

In August, Waters announced its UNIFI MS data acquisition system is now compatible with Molecular Discovery's Molecular Mass-MetaSite and WebMetabase metabolite identification and processing platform. This is the first time that the UNIFI API has been made accessible to an outside party.

In August, **Newomics** closed a \$3.9 million series A funding round. According to the company, its Newomics M3 is the first commercial multi-nozzle emitter device for MS.

Intabio received a \$2.3 million Fast Track Small Business Innovation Research (SBIR) grant in August from the NIH's National Center for Advancing Translational Sciences. The grant will fund development of the Blaze system, a microchip-based technology designed to integrated capillary isoelectric focusing (cIEF) and MS for separation and imaging of protein isoforms, and MS sample preparation and delivery.

Product Introductions

In August, Knauer introduced the KNAUER 4000 MiD single quadrupole MS system, expanding its preparative HPLC portfolio to the field of mass-directed purification.

Shimadzu released in August IMAGEREVEAL MS imaging data analysis software, enabling data to be analyzed from a variety of perspectives and featuring six types of functionality for data analysis.

In August, Thermo Fisher Scientific launched the Thermo Scientific FAIMS Pro Interface for use with its Thermo Scientific Orbitrap Fusion Lumos Tribrid or Thermo Scientific Orbitrap Fusion Tribrid. It is designed to reduce sample and spectral complexity, improve selectivity and increase coverage of the proteome.

Sales and Orders of Note

In June, CAMECA announced that the Key Laboratory of Isotope Geochemistry of the Guangzhou Institute of Geochemistry, Chinese Academy of Science has ordered a NanoSIMS 50L.

Sample Preparation

Company Announcements

ADS Biotec entered into a strategic partnership in June with Kurabo Industries' Bio-Medical Division to sell and supports Kurabo's QuickGene line of Nucleic Acid Isolation systems and consumables in North America and Europe.

In July, **Diversigen** and **Norgen Biotek** announced a strategic partnership for a comprehensive solutions for microbiome analyses. Their combined offering includes sample collection, ambient temperature stabilization for transport of samples, purification of inhibitor-free nucleic acids from these samples, library preparation kits, and bioinformatics and analysis capabilities for preclinical and clinical specimens.

Entopsis licensed in July its PCRopsis product line to **Beijing Wan Bridge Intelligent Technology** and will receive a minimum of \$2.8 million in revenue over three years. The product line consists of the PCRopsis Cell for direct PCR from cellular samples without DNA isolation or centrifugation in under 20 minutes; PCRopsis Blood Cell Separator for separation of white blood cells, or specific cell types, from red blood cells starting with whole blood; and PCRopsis Concentrator, which concentrates DNA, proteins and cells within five minutes without the need for equipment.

Strategic Directions International, Inc.

Reported Financial Results

\$ USD in Millions	Period	Ended	Sales	Chg.	Op. Prof.	Chg.	Net Prof.	Chg.
Becton, Dickinson (Life Sciences)	Q3	30-Jun	\$1,079.0	8.2%	\$241.0	21.1%	NA	NA
Bio-Techne	Q4	30-Jun	\$180.3	15.1%	\$42.9	7.2%	\$40.9	48.1%
Bio-Techne (Biotechnology)	Q4	30-Jun	\$115.0	18.3%	\$55.3	15.8%	NA	NA
Bio-Techne (Protein Platforms)	Q4	30-Jun	\$32.3	20.8%	\$6.4	46.6%	NA	NA
Bio-Techne (Diagnostics)	Q4	30-Jun	\$33.1	1.7%	\$10.7	2.1%	NA	NA
Bio-Techne	FY	30-Jun	\$643	14.2%	\$136.2	12.9%	\$123.4	62.1%
Bio-Techne (Biotechnology)	FY	30-Jun	\$422	15.6%	\$199.1	13.7%	NA	NA
Bio-Techne (Portein Platforms)	FY	30-Jun	\$112	22.3%	\$18.0	86.5%	NA	NA
Bio-Techne (Diagnostics)	FY	30-Jun	\$110	2.8%	\$28.3	-1.0%	NA	N/A
Luminex	Q2	30-Jun	\$79.6	4.1%	\$7.9	5.0%	\$5.7	2.3%
Repligen	Q2	30-Jun	\$47.7	47.1%	\$4.3	-21.9%	\$2.7	-67.6%
Xylem (Measurement & Control Solutions)	Q2	30-Jun	\$383.0	19.3%	\$31.0	6.9%	NA	NA
Other Currencies in Millions								
Expedeon	Q2	30-Jun	€3.3	105.7%	-€0.6	29.4%	-€0.2	91.7%
Scientific Digital Imaging	FY	30-Jun	£14.5	34.9%	£1.8	84.2%	£1.6	95.0%
Takara Bio (Bioindustry)	Q1	30-Jun	¥6,516	10.7%	¥0.7	-40.9%	NA	NA
Tecan	H1	30-Jun	CHF 273.5	8.4%	CHF 37.8	26.3%	CHF 29.2	12.1%
Tecan (Life Sciences)	H1	30-Jun	CHF 148.7	3.7%	CHF 18.1	1.7%	NA	NA
Tecan (Partnering)	H1	30-Jun	CHF 133.7	16.4%	CHF 25.6	32.2%	NA	NA

NA = not available, *NM* = not meaningful

