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Strategic Directions International, Inc.

# INSTRUMENT BUSINESS OUTLOOK



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Strategic Information for the Analytical & Life Science Instrument Industry

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## Potency Testing a High Priority for Cannabis Industry

The US cannabis industry has come a long way in the last two decades. In 1996, California legalized medical cannabis, pioneering a dialogue on cannabis research, testing and regulation. The industry experienced its next groundbreaking development in 2012, when Washington and Colorado legalized the sale of recreational cannabis, a move that eventually gained traction in other states over the next few years. As of 2017, recreational cannabis sales are legal in DC, Oregon, Nevada, Maine, Massachusetts, Alaska and California, while many other states have legalized medical cannabis, including Montana, Arizona, New Mexico, New York, Illinois, Michigan, Louisiana and

Florida. The noticeable trend of the legalization of medical and recreational cannabis across the US has opened a variety of testing opportunities for laboratory product and analytical instrument companies, as the cannabis market, though burgeoning, is slated for stellar growth.

As a growing market, the cannabis industry has thus far lacked official standards or references for testing, largely due in part to the fact that its use and research is not yet federally legal. However, cannabis industry players are slowly making their moves towards understanding and standardizing the science around cannabis testing to ensure the legitimacy of the industry.

Early last month, the Association of Official Analytical Chemists International (AOAC) announced that it will work alongside industry partners, such as instrument companies and testing labs, to develop and finalize Standard Method Performance Requirements (SMPRs) for cannabis potency. Chaired by Susan Audino, of S.A. Audino & Associates, the AOAC Working Group on Cannabis Potency is part of the AOAC Stakeholder Panel on Strategic Foods Analytical Methods (SPSFAM) and is working towards creating fit-for-purpose methods for potency testing.

Dr. Audino discussed with **IBO** how her work with the AOAC began during an AOAC meeting in 2015, when she served as the chair of a symposium regarding the scientific and analytical challenges of the cannabis industry. “My concern was that the community was ambivalent about becoming involved in the cannabis sector, thereby missing an opportunity and obligation to address scientific needs,” she explained. The symposium was extremely well-received, and Dr. Audino consequently worked with Dr. E. James Bradford, executive director of the AOAC, to secure six Organizational Affiliates (OAs) that were open to creating and funding a Cannabis Advisory Panel. OAs are “a cross-sector group representing food and beverage, dietary supplements, government agencies, technology providers, ingredient suppliers, contract research organizations, and test kit manufacturers,” according to the AOAC. In summer 2016, the first meeting with the OAs took place, with the conclusion to approach the SPSFAM with a proposal during the annual AOAC meeting that year. With the proposal also received positively, the Panel held bimonthly meetings to create SMPRs for cannabis potency, with two established in fall/winter 2016: potency in plant material and potency in concentrates.

According to Dr. Audino, as of the publication date of this **IBO** article, there are not yet any existing finalized standard methods on cannabis testing from any official organization. The Panel Dr. Audino helped spearhead decided to focus on developing standards for an aspect of cannabis that would carry the most weight in the industry, and chose potency. “Potency is an important methodology to develop because it has such great impact for the medicinal population, recreational population and, to some extent, in the regulatory communities,” Dr. Audino stated. “Once the team decided on potency, we identified which of the tens of phytocannabinoids we thought were most important to consider, and we developed a list of approximately 15 key phytocannabinoids.”

Of the 15 phytocannabinoids, the working group narrowed the testing focus to five: THC, THCA, CBD, CBDA and CBN. As Dr. Audino stated, these five phytocannabinoids were chosen due to their importance in the cannabis industry and the availability of certified reference standards.

The OA instrument companies that are part of the working group are SPEX, Sigma-Aldrich, SCIEX and CEM. According to Dr. Audino, initially, the working group approached potential OAs to assess if the companies were interested in devising analytical testing methods and, if so, if they would be willing to provide financial support for the project. The aforementioned companies are part of the very first AOAC Cannabis Advisory Panel, a major development for the future of cannabis testing methods. “This panel in particular represents the different facets of the AOAC that are critical to cannabis-centric method development: instrument, ancillary equipment, certified reference materials, consumable chemicals and an analytical testing lab,” Dr. Audino explained. “Not all organizational affiliates were in a position to fund this Advisory Panel at the time it was formed, and we are hopeful they will find resources in the future.”

Also part of the OAs of the cannabis potency working group is GW Pharmaceuticals, a biopharmaceutical company focusing on cannabinoid-based medicines, and California-based cannabis testing lab, SC Labs. Josh Wurzer, co-founder and Laboratory Director of SC Labs, discussed with **IBO** the role that SC Labs is playing in the AOAC working group, explaining that SC Labs has been testing cannabis since the inception of the cannabis testing industry. “In the beginning, it was a big hassle that we had zero reference methods,” Mr. Wurzer said. “Here we are, eight years later, and we still have no reference methods and very little in the way of published methods that apply to what we do.” When SC Labs became aware of the AOAC’s interest in developing reference methods for cannabis and was looking for OAs, the company jumped on board.

SC Labs has received much interest from instrument companies in collaborating on method development, though the interest varies from vendor to vendor. “Most of the larger companies wouldn’t even sell equipment to the cannabis testing market just a few years ago, and some still won’t,” said Mr. Wurzer. In the last couple years, however, Mr. Wurzer notes that there has been a move towards opening up to the cannabis industry. “The companies that embraced our industry early on definitely have a head start,” he noted. “Politics has even played a part. With the uncertainty for our industry caused by the recent elections, some manufacturers have backed off of planned projects.”

According to Mr. Wurzer, SC Labs was the first lab to test for residual solvents in extracts of cannabis. The lab also had the first test for pesticides that was sensitive enough to detect pesticides in cannabis and cannabis-derived products on a regular basis. “Many labs were testing for the wrong pesticides, and our strong background in and connection to the cultivation industry helped us develop a test that was actually relevant to the plant,” Mr. Wurzer explained. “There are a handful of pests that attack cannabis, and if you don’t look for the pesticides that kill those pests, your test is not very useful.” As Mr. Wurzer noted, in the initial stages of testing, SC Labs was detecting pesticides in almost 50% of samples tested.

SC Labs then developed validated methods and attempted to convince retailers to test the cannabis they sold. “It was a lot of work early on to convince people to give us their valuable product and pay for the test with the distinct possibility that they would be told that the product was unsafe,” he said. Although the number of samples with detected pesticides has dropped, Mr. Wurzer states that a large portion of the market is still dealing with cannabis that has pesticide contamination levels that would be inadmissible in other states; this can suggest that pesticide testing is a potential growth opportunity for instrument companies.

Generally, testing labs can each have their own standards, which may or may not be adopted by other labs. “We have our own methods for potency, which are proprietary,” said Mr. Wurzer, adding that this is not unusual in the analytical testing industry. “What is different is that we don’t have a good industry mechanism for ring testing for our cannabinoid assay (or most of the other tests we perform for that matter).”

Another issue, he states, is the lack of official reference methods for the cannabinoid assays. “The advantage of having industry-accepted reference methods when most labs will develop their own anyways is that reference methods become a baseline for performance,” he explained. “If a lab is going to develop a proprietary method (and most do), it better outperform the appropriate reference method.”

Though SC Labs has its own testing methods, the lab has not published them yet, so the methods have not been adopted by other labs; however, the company plans on submitting its methods to the AOAC as an OA of the cannabis potency working group, as SC Labs is working on a more collaborative effort to progress the cannabis industry. “Over the past couple years, we have come to the conclusion that the advantages of sharing our data and methodology is beneficial to our company,” said Mr. Wurzer. “The better our competitors do, the more faith the broader industry has in testing, which is beneficial to us.”

Based on the OAs involved in the working group, it can be deduced that the SMPRs include a workflow that is to be standardized, from sample preparation to detection. Dr. Audino points out that although the instruments used for cannabis potency testing are not new by any means, the complexity of the matrices in the plant can be a challenge for most analytical labs. “The cannabis plant is highly complex and heterogeneous, particularly between hybrid plants,” Dr. Audino explained. “Challenges begin with bulk sampling, sub-sampling, then sample preparation.”

Mr. Wurzer also detailed the complicated sample preparation techniques used by SC Labs, explaining how the sample must first be properly extracted into an appropriate solvent for HPLC analysis. “We use bead beaters for tissue disruption, and then there are several dilution steps, the addition of internal standard and filtering,” he said.

Since the matrices of the cannabis plant are so complex, it is extremely important to use the appropriate instrument that is sensitive enough for potency testing. SC Labs uses HPLCs with UV detectors for cannabinoid testing. Although GC is commonly cited as a tool for cannabis analysis, as Mr. Wurzer indicated, GC was mentioned in early published methods due to the fact that initial methods were chiefly intended for forensic testing. “Since the cannabinoids are very heat sensitive, GC does not work without complicated derivatization steps,” Mr. Wurzer explained. “We use GC with either FIDs or MS for residual solvents and terpenes, and LC/MS for pesticides,” he said. “We use both qPCR and media-based assays for microbiological testing.”

Although LC/MS can be used, SC Labs does not use LC/MS for potency testing. “LC/MS is overkill for potency

testing and underperforms HPLC/UV,” Mr. Wurzer said. “HPLC/UV has better accuracy, precision, a greater linear range and is more rugged than LC/MS.” He added, “Plus, if you use DAD and get a spectra of each peak, you still get a secondary confirmation on identity.”

The federal prohibition of cannabis is not helping matters, as companies and labs can be limited in their reach. “Cannabis testing labs are not able to participate in traditional proficiency test schemes and are not able to access known standard reference materials in desired matrix, thereby making suitable and appropriately characterized surrogate materials difficult to locate,” Dr. Audino said.

SC Labs is also tackling the federal prohibition of cannabis by reaching out to law enforcement, inviting officials to a tour of the lab to see the work of the testing company. “Even if they don’t support the movement, people generally agree that there should be a quality control component,” Mr. Wurzer said. “Now, we see a lot more support from mainstream industry and people like the AOAC.”

Embracing the need to develop SMPRs for cannabis testing is a major move by the AOAC, and signifies the slow but sure growth of the cannabis industry. “It is [the Panel’s] hope for the cannabis methods development to continue to gain in momentum and interest such that an independent stakeholder panel can be formed,” Dr. Audino stated.

The AOAC’s decision to create cannabis potency standards has also provided support to testing labs like SC Labs, after the lab spent many years on “the fringes of the analytical community,” as Mr. Wurzer stated. “It has been really great to see organizations like the AOAC, the American Chemical Society, the American Herbal Products Association and the American Herbal Pharmacopoeia embracing cannabis,” he said. “Anything we can do to shepherd the cannabis industry into the mainstream is a worthwhile endeavor, as far as we are concerned.”

According to Dr. Audino, the Cannabis Advisory Panel has also recently added other aspects of cannabis testing on its agenda. “The Advisory Panel recently decided to advance efforts to pesticides and some edible matrices, again anticipating the development of two SMPRs between the 2017 mid-year and 2017 annual meetings,” she said. “The canvas is quite large and the need for method development is just as large; there is a lot of work ahead of us, and we will continue to address important matrices and analytes [in cannabis testing].”

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## SLAS 2017: New Product Families Unveiled

The annual SLAS conference and exhibit was held February 4-8 in Washington, DC. Attendance was down 19.3% from last year, when the show was held in San Diego, California (see *IBO* 1/31/17), but boasted an additional 400 participants compared to 2015, when the show was last held in Washington, DC (see *IBO* 1/30/15). The West Coast edition of the show is typically more popular, according to SLAS. The number of exhibitors fell 8.1% to 320. SLAS 2018 will be held February 3-7 in San Diego, California.

In a presentation to SLAS exhibitors, SDi highlighted market data and trends for five categories of life science instrumentation and product markets: genetic assays and technologies, cellular and biochemical assays, and automation and equipment. The fastest growing markets over a five-year period within these categories are expected to be imaging techniques, cellular and biochemical assays, and analytical technologies.

Among the regular exhibiting companies was Corning Life Sciences. Speaking with *IBO*, Richard Eglen, PhD, president of Life Sciences and General Manager of Life Sciences for Corning, discussed the company’s ability to develop the 3-D cell culture market. Its products include spheroid plates, which enable automation and scalability, and other consumables, as well as software, and live-cell imaging systems.

There were a number of new products that debuted at show, many targeting NGS, cell analysis and protein characterization. The show is a major exhibition for liquid handling and sample management systems. In recent years, biosensor and cell analysis products have also become an increasing focus due to the evolution of drug discovery and development.

### Liquid Handling

At SLAS 2017, **Beckman Coulter Life Sciences** re-emerged as an innovator in automated liquid handling with the

launch of the Biomek i-Series Automated Workstations. These systems are the first major addition to the company's Biomek liquid handling platform in 13 years. The new designs reflect input from customers around the world for solutions that provide enhanced protocol flexibility.

The Biomek i5 Workstation has 25 deck positions; the Biomek i7 Workstation has 45 deck positions that can support higher-throughput and more complex workflows. Both the Biomek i5 and i7 Workstations have a large-volume, 1 mL multi-channel pipetting head; a rotating gripper; a 4D-open platform design; onboard cameras; a bright, multiple color status bar; and internal LED light. Both the Biomek i5 and i7 Workstations can support a wide range of research and drug discovery applications including cell-based assays, high-throughput screening, high-content screening, cell line development, proteomics, 3D cell models and compound handling. Likewise, both systems can support genomics applications that range from NGS sample preparation, nucleic acid sample preparation and qPCR/PCR set-up, to microarray sample preparation for genotyping and gene expression analysis.

According to Robert Lund, senior manager, Product Management, at Beckman Coulter Life Sciences, the Biomek i5 workstation will cost between \$75,000 and \$100,000, and the larger Biomek i7 workstation will cost up to \$175,000, depending on how each workstation is configured. Orders were accepted beginning the week of February 13, with first shipments starting in early April.

**TTP Labtech** debuted its Dragonfly Discovery instrument for automated low-volume liquid handling. The new platform enables rapid and reliable low volume (200 nL and upwards) dispensing using positive displacement. Positive displacement offers highly accurate dispensing of low liquid volumes. The instrument can dispense on a variety of different formats, up to 1,536 wells, making it ideal for assay development labs. The instrument is priced at \$100,000, and full launch is anticipated for late 2017.

The AcouTrap 2.1 from **AcouSort** is a benchtop automated system for trapping, enrichment and dispensing of cells, extracellular vesicles and particles into well-plates. The AcouTrap 2.1 uses acoustofluidics, which uses standing acoustic waves to separate and trap particles based on their size, compressibility and density. Acoustic trapping enables handling of extremely small volumes with minimal damage to cells, delicate particles or vesicles. It is designed for basic research applications, including isolation and enrichment of rare cell populations. The use of acoustic trapping allows users to avoid ultracentrifugation, leading to faster sample processing and higher recovery rates. Additionally, the AcouTrap 2.1 system offers automated sample processing, leading to increased throughput. The system is currently available in Europe for €50,000 (\$55,556 = €0.90 = \$1). International sales are expected to coincide with SLAS.

## Analysis

The BioSpa Live Cell Imaging system from **BioTek Instruments** was presented at SLAS 2017. The BioSpa integrates several pieces of BioTek's technology into a complete solution for precise environmental control and monitoring of live-cell assays, coupled with live-cell imaging. The system can monitor and maintain cultures for up to two weeks, and it can send email and text notifications. Live-cell imaging capability is up to 60x magnification. System prices range from \$80,000 to \$120,000.

At SLAS, BioTek also exhibited its Lionheart platform, optimized for live-cell imaging. This sleek and compact system offers imaging using fluorescence, phase contrast, brightfield or color brightfield from 1.25x to 100x oil magnification. Fluorescent imaging is available in 4 different colors for up to 18 different fluorophores. The augmented microscopy platform simplifies the process from imaging to publishing, automating and streamlining the image processing and analysis capabilities. The Lionheart platform starts at \$55,000.

**Nanomedical Diagnostics'** Agile R100, is a lower-cost, compact, label-free biosensor assay based on Field Effect Biosensing (FEB), an all-electronic method for measuring biomolecular interactions. Current is measured across the surface of a FEB sensor on which capture molecules are immobilized. Any interaction or binding with the capture molecule on the surface causes a change in conductance that results in measurable changes in current. This design allows the Agile R100 to detect target small molecules that interact with the capture molecule, even in crude media, complex matrices and tissue lysates.

Users can directly pipette their samples onto the chip surface, with volumes as low as 10 µL. Unlike many competing label-free biosensor systems, the Agile R100 is graphene based and does not use an optical-based method of detection. The Agile R100 is intended for use in pharmaceutical applications, particularly in small molecule or protein lead discovery and biologics activity quality assurance. The Agile R100 has been available since September

2015 and costs \$20,000. Multiplex chips for the system average \$75 and single plex chips average \$15.

**Berkeley Lights** (BKI) launched its first commercial platform, the Beacon, in December 2016. The Beacon platform is a closed nanofluidic environment with a structured-light optical engine that enables fully automated nanoscale cell assays. The backbone of the system is the BLI Opto-Fluidic Chip. Using semiconductor technology, an array of phototransistors is patterned onto a silicon substrate. Structures, called NanoPens, are built on the substrate for cells to be placed. When activated by structured light, a local electric field is created that can manipulate cells (or beads) in fluid. NanoPen structures allow for single-cell (clonal) isolation and expansion, as well as single cell/clonal-cell assays. The BLI Opto-Fluidic Chips comes in two sizes: one with 1,500 NanoPen chambers and the other with 3,000 NanoPen chambers. Each chamber can hold 1 nL of fluid.

Cells are manipulated on the chip using OptoSelect visible light technology. Cells or beads in liquid are repelled by a light-induced electric field (OptoElectroPositioning); the field can be turned off or on using a computer algorithm to allow for precise and parallel manipulation. At the heart of the system is an epifluorescent microscope that captures bright field and fluorescence images of the cells in each NanoPen chamber. The system monitors each chamber so that each clone's growth, phenotype and functionality can be visualized and measured on a daily or hourly basis.

Troy Lionberger, PhD, Technology Lead, Single Cell Applications, at BKI, explained that the Beacon platform can be used to accelerate the time that it takes to identify high producing clones in a cell line-development workflow, from 10-15 weeks down to 5-7 days. He also said that the Beacon confirms what many development scientists had suspected, that high producing cells are often the clones that grow somewhat slower. A wide variety of other cell assays can be performed, including surface markers, phenotypic assays, live/dead assays, reporter cell assays, etc. The Beacon instrument can run four Opto-Fluidic chips simultaneously. Each chip, regardless of size, costs \$1,500. The Beacon instrument platform costs \$2 million.

## Sample Preparation

**Thermo Fisher Scientific** presented the KingFisher Presto system, which uses magnetic particle-based technology for automated nucleic acid and protein purification. The instrument is designed to integrate with other parts of an automated workflow, including liquid handlers and robotic arms. The new system offers fast nucleic acid recovery, taking 45 minutes to 1 hour to purify DNA in a 96-well plate. The KingFisher Presto is compatible with Thermo Fisher's MagMAX Cell-Free DNA isolation kits. Launched in September 2016, the system's list price starts at \$40,000.

Launched by **Analytik Jena** in Europe last year and now available in the US, SmartExtraction kits are designed for high-yield extraction of high-molecular weight DNA. Due to the integration of the extraction surface (Smart Modified Surface) within the pipette tip, DNA extraction is performed by pipetting up and down alone, eliminating the need for centrifugation, magnets, resuspension and plate manipulation. By reducing these steps, 8-96 samples can be run in 24 minutes. SmartExtraction kits are available for a variety of automated liquid handling systems with 1 mL pipetting heads, including the CyBio SELMA, CyBio FeliX and GeneTheatre from Analytik Jena, but are also compatible with systems from other manufacturers. Pricing varies depending on kit size and type, with four kit types currently available: smart Blood DNA Midi prep, smart DNA prep, smart Bacteria DNA prep and smart Yeast DNA prep.

## Sample Management

Available in 2017, **Hamilton Storage**'s SAM HD is a small, automated sample management system intended for sample storage in biobanking, forensics, drug discovery and pharmaceutical applications. Several models of SAM HD will be available for storage at +4°C, -20°C, -40°C and -80°C, with capacity of up to 60,000 tubes in standard racks or 86,250 tubes using Hamilton Storage's high-density SBS-compliant RackWare racks. The SAM HD includes a touchscreen PC with INSTINCT S software, allowing for programming directly at the storage unit, including chain-of-custody permissions. A high-quality camera inside of the unit with wide field of view simplifies sample picking. The SAM HD can be integrated with LIMS systems, allowing for management and tracking of samples throughout the lab.

## Sample Handling

**Thermo Fisher Scientific** presented a new instrument for tube capping and de-capping, the Automated Decapper 550. This instrument offers capping and de-capping for medium- to high-throughput labs for up to three different tube types. An integrated barcode scanner is an optional add-on to the instrument. The Decapper 550 list price is \$35,000 without a barcode scanner and \$45,000 including a barcode scanner.

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## Thermo Fisher Scientific to Acquire Finesse Solutions

*Waltham, MA 2/13/17; Waltham, MA 2/14/17*—Thermo Fisher Scientific has acquired bioprocess-management technology firm Finesse Solutions. Financial details were not disclosed. Finesse Solutions generated 2016 revenues of \$50 million, and provides sensors, controllers and software. “Finesse Solutions has developed a universal control system that will combine seamlessly with our existing single-use technologies to strengthen our position in the high-growth bioproduction market,” stated Thermo Fisher President and CEO Marc N. Casper. Finesse Solutions will join Thermo Fisher’s Life Sciences Solutions Segment.

*Thermo Fisher and Finesse Solutions have been partners since 2013 under a supply agreement covering their respective bioreactors, and sensors and control systems. The acquisition adds proprietary bioprocess software and sensors to Thermo Fisher’s Bioproduction business. Endress+Hauser was among Finesse Solutions’ largest investors.*

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## LGC Adds to Proficiency Testing Labs

*Teddington, UK 2/1/17*—LGC has acquired API Food Quality, a US-based accredited proficiency testing (PT) organization. API Food Quality customers include over one thousand food labs in 30 countries. Financial details were not provided. In connection with the purchase, LGC has formed the American Proficiency Institute, made up of API Food Quality and LGC’s existing US PT business. “We are delighted to be adding API Food Quality to our Standards division. It offers a highly complementary fit to our existing global PT capabilities, while creating a North American counterpart to our existing PT hub locations in Bury, England and Johannesburg, South Africa,” stated Euan O’Sullivan, managing director of LGC’s Standards Division. Daniel C. Edson, API Food Quality cofounder and president, will lead the new business.

*Proficiency testing, or inter-laboratory comparison, is used to determine lab performance. API Food Quality provides chemistry and microbiology PT schemes for food, expanding LGC’s existing offerings in these areas. LGC’s previous PT acquisitions included Thistle QA in 2015 (see **IBO** 11/15/15) and Analytical Reference Materials International in 2012.*

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## IDT Expands Asia-Pacific Oligo Business

*Skokie, IL 2/8/17*—Integrated DNA Technologies (IDT), a provider of custom nucleic acid products for life sciences, has acquired GeneWorks’ oligonucleotide manufacturing business for an undisclosed amount. GeneWorks is based in Australia. “With this acquisition, we are furthering our goal of making our world class products and services more easily accessible to scientists around the world. We look forward to availing GeneWorks’ customers of our unrivaled manufacturing capabilities, design expertise and fast turnaround times,” commented IDT Founder and CEO Dr. Joseph A. Walder.

*Geneworks’ oligonucleotide manufacturing is based in Australia. This is IDT’s third Asia Pacific-based acquisition in two years (see **IBO** 12/1/15, 6/15/16), as the company continues to build a foothold in the region, targeting oligonucleotide manufacturing capacity and distribution.*

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## Anatrace Buys UK Firm

Los Angeles, CA 2/14/17—Anatrace, a provider of detergents and synthetic lipids for membrane protein research, has acquired Molecular Dimensions for an undisclosed amount. UK-based Molecular Dimensions supplies modern screens, reagents, other consumables and instruments for structural biology research. “Most of us may understand that drug discovery is a long and arduous multi-year process, but what is less known is that many of the specific drug targets are proteins. With the addition of Molecular Dimensions, we will be able to offer a more complete portfolio of tools that aid and support drug discovery, disease prevention and cure,” said Anatrace CEO Ben Travis. Brian Wall, founder and CEO of StoneCalibre, which owns Anatrace, commented, “We will continue to look for additional strategic acquisitions in the life science tools and diagnostics industry that could enhance the geographic presence, bolster the product and service offering and complement the organic growth of the companies.”

*Molecular Dimensions’ products support research using X-ray crystallography, complementing StoneCalibre/Anatrace’s 2015 purchase of Microlytic, which provides solutions for soluble protein crystallization (see IBO 3/15/15).*

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## Applied BioCode Goes Public

Santa Fe Springs, CA 2/9/17—Applied BioCode, a provider of Barcoded Magnetic Bead and detection systems for multiplexed nucleic acid and protein detection assays, has completed an IPO on the Taiwan Emerging Market Stock Exchange. The company operates as a registered Cayman Island corporation, and has facilities in the US and Taiwan. “This will enable Applied BioCode to gain access to additional capital in order to accelerate the commercialization of the BioCode MDx 3000 High Volume Molecular Diagnostics System with 18-plex Gastrointestinal Panel into the US market, and we anticipate FDA clearance later this year,” stated Applied BioCode President Dr. Winston Ho.

*The company’s technology utilizes up to 4,096 digital barcodes. For the research market, Applied BioCodes provides the BioCode 100A and 2000 Analyzers, as well as cytokine/chemokine multiplex immunoassays. For this market, it has licensed its technology to Molecular Devices and LGC (formerly Douglas Scientific).*

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## Fourth Quarter 2016 Sales Show Faster Growth

### Microarrays Boost Illumina Growth

#### Q4 2016

After lowering guidance in the third quarter, fourth quarter 2016 sales for Illumina came in ahead of company expectations. Sales advanced 4.7% for the quarter to \$619.3 million, led by demand for sequencing consumables and microarrays.

Total microarray sales climbed 14% to account for 16% of revenues. Growth was driven by a strong backlog, healthy year-end spending and robust consumer sales, which jumped more than 60%. Demand was particularly strong for the Infinium XT line of products and Global Screening Arrays.

Sequencing revenue improved 3% to make up 84% of sales. Sequencing consumables revenue advanced 20% to \$331 million, led by sturdy NextSeq and HiSeq X utilization. As expected, sequencing instrument sales declined 23% to \$111 million as a result of lower HiSeq X placements. However, MiSeq shipments remained steady, and NextSeq sales and orders grew sequentially led by demand from NIPT customers in the US and China. MiniSeq placements remained healthy, as the company shipped more than 110 units for a total installed base of 370 systems. The

company also noted that it discontinued its NeoPrep system, which, according to a customer letter, was in part attributed to sample inconsistencies.

Geographically, Asia-Pacific remained robust, as sales in the region climbed 29%, including roughly 50% growth in China. European sales, which benefited from year-end spending, advanced 11%. In contrast, sales in the Americas, which started the year with double-digit growth, declined 4% due to slower instrument sales.

Adjusted gross margin contracted 173 basis points to 69.5%. Given the increased investment in genetic startups, manufacturing and headcount, adjusted operating margin fell 223 basis points to 25.1%.

| Illumina FY16   |            |             |           |            |             |           |
|-----------------|------------|-------------|-----------|------------|-------------|-----------|
|                 | Q4         |             |           | FY         |             |           |
|                 | Rev. (\$M) | Rev. Growth | % of Rev. | Rev. (\$M) | Rev. Growth | % of Rev. |
| Consumables     | \$406.9    | 17.2%       | 66%       | 1544       | 21%         | 64%       |
| Instrument      | \$113.9    | -22.8%      | 18%       | 470        | -21%        | 20%       |
| Other Products  | \$4.8      | 48.4%       | 1%        | 19         | 18%         | 1%        |
| Service & Other | \$93.8     | 0.1%        | 15%       | 366        | 11%         | 15%       |

## 2016

For the year, Illumina sales climbed 8.0% to \$2.40 billion, but was well below the company's initial outlook due to slower-than-anticipated demand for high-throughput systems. Nevertheless, consumables demand remained strong, driven by NIPT and oncology testing. Total sales for oncology applications advanced 20% to account for 10% of company revenues. Overall, Product sales grew 7%, and Service and Other revenue improved 11% to account for 85% and 15% of revenues, respectively.

Sequencing sales expanded 6% to make up 84% of revenues. This growth was driven by consistent consumables demand, for which sales advanced 23%. The shift of NIPT customers in China moving to in-house testing boosted consumables sales but hampered demand for sequencing services, for which sales grew in the low single digits. Given the strong comparison for high-throughput systems, sequencing instrument revenue slumped 22%. The company hopes to reinvigorate sales for this market with its new NovaSeq system. The company ended the year with 37 HiSeq X systems in backlog, of which a majority are expected to transition to the NovaSeq.

Microarray sales jumped 19% for the year to account for 16% of revenues. With a strong backlog, microarray sales are expected to growth in mid- to upper single digits.

Sales in Asia-Pacific grew roughly 20.2%, including significant growth in China due to funding for the Precision Medicine Initiative, as well as strong NIPT and oncology testing. US and European sales were 7.2% and 4.9%, respectively. Sales to Other regions declined 10.3%.

Adjusted gross margin slipped 58 basis points to 71.3%, and adjusted operating margin contracted 418 basis points to 26.3% because of increased investments.

Full-year 2017 sales are projected to grow 10%-12%, including less than 1% growth from each Helix and GRAIL, and currency headwinds of roughly 1%. However, first quarter sales are projected to grow 3% to \$580-\$595 million, as the transition to the NovaSeq platform is expected to temporarily impact demand for instruments and consumables.

## PerkinElmer Expands Margins

### Q4 2016

Fourth quarter 2016 adjusted organic sales for PerkinElmer grew 1% to \$567.0 million, which was towards the low end of company guidance due to continued weakness in the industrial and environmental markets, as well as delayed product launches. During the quarter, the company divested its Medical Imaging business (see *IBO* 12/31/2016), currently moved into discontinued operations and realigned its organizational structure into two segments: Discovery & Analytical Solutions (DAS) and Diagnostics (see *IBO* 9/30/16).

DAS sales declined 1% organically to account for 72% of revenues. This decline was primarily attributed to lower demand for analytical equipment from industrial and environmental markets, for which sales declined in the mid-single digits each. Biopharmaceutical sales grew only low single digits, driven by strength in the OneSource business. Given a weak comparison, academic sales grew in the mid-single digits. Finally, food sales were particularly strong with growth in the low teens.

Sales for the Diagnostics segment, which is now primarily focused on reproductive health, infectious disease and oncology, climbed 7% organically to make up 18% of sales. The oncology-related business, which includes microfluidics and automation technologies for NGS, which were previously part of the Life Science and Solutions business, grew in the high single digits. Reproductive health sales were also strong, driven by demand in China and the Americas.

Geographically, sales in Asia grew in the high single digits. European sales were flat, and sales in the Americas declined in the low single digits due to weak industrial demand. Sales in the BRIC region (Brazil, Russia, India and China) expanded in the high single digits but were mixed. Demand in China was strong for diagnostics and analytical products, while India sales grew double digits within the DAS segment. Conversely, sales in Brazil and Russia declined.

Adjusted gross profit margin expanded 96 basis points to 50.1% due to productivity improvements and product mix. Adjusted operating margin improved 57 basis points to 21.3%

| Non-GAAP PerkinElmer FY16        |            |           |             |            |           |             |
|----------------------------------|------------|-----------|-------------|------------|-----------|-------------|
|                                  | Q4         |           |             | FY         |           |             |
|                                  | Rev. (\$M) | % of Rev. | Org. Growth | Rev. (\$M) | % of Rev. | Org. Growth |
| Discovery & Analytical Solutions | \$409.9    | 72%       | -1%         | \$1,513.0  | 71%       | 0%          |
| Diagnostics                      | \$157.0    | 28%       | 7%          | \$603.2    | 29%       | 8%          |

## 2016

Full-year adjusted sales improved 2% organically to \$2.12 billion. Growth was driven by strength in the food analysis and reproductive health businesses. Food safety sales grew in the low double digits to account for 8% of total revenues. Biopharmaceutical sales increased in the low single digits, as higher service revenues was hampered by demand for plate readers and radiochemicals. Academic, environmental and industrial sales declined in the low- to mid-single digits each.

Organic DAS sales were flat for the year to account for 71% of revenues. Diagnostics revenue advanced 8% organically to make up 19% of sales, led by low double-digits sales growth in the newborn screening business.

Sales in Asia grew double digits, were flat in Europe and declined low single digits in the Americas. BRIC sales increased in the low double digits, including low- to mid-teen sales growth in China and India each. Sales in Russia were flat but declined double digits in Brazil. Overall, total sales to emerging markets improved in the high single digits.

Adjusted margins improved 114 basis points to 49.4% as a result supplier consolidation, increased regional production in China and divestments. Aside from the Medical Imaging business (see *IBO* 12/31/16), the company also divested NTD Labs (see *IBO* 4/30/16) and LABWORKS (see *IBO* 4/30/16) during the year. Adjusted operating margin advanced 135 basis points to 18.6%.

The company expects similar end-market growth in 2017, but with positive industrial and environmental sales growth as a result of improved execution and new products. As such, 2017 organic sales are projected to increase 4% to \$2.19- \$2.20 billion. This outlook includes 7% and 3% organic growth for the Diagnostics and DAS segments, respectively. Geographically, sales are expected to grow low- to mid-single digits in the US, low single digits in Europe and high single digits in the APAC regions. First quarter sales are projected to grow 2%-3% organically to \$500-\$510 million.

# Life Science Demand Grows for Thermo Fisher Scientific

## Q4 2016

Fourth quarter 2016 sales for Thermo Fisher Scientific expanded 6.5% to \$4.95 billion but were flat organically. Acquisitions contributed 8% to revenue growth, while currency headwinds reduced sales by 1%. Organic growth was muted due to fewer billing days, offsetting the favorable impact of additional selling days in the first quarter of 2016. Accordingly, sales growth based on normalized days advanced 4%, driven by continued strength in biopharmaceutical markets and in Asia. All sales figures below are based on organic normalized days.

Despite a strong comparison, biopharmaceutical sales climbed 9%. Academic and government sales grew in the low single digits, led by demand in the US and China. Industrial and applied markets grew at a similar low single-digit rate, as strength in applied markets for food safety and environmental applications was offset by core industrial demand. However, the company reported improved industrial orders. Diagnostics and healthcare sales improved 3%.

Life Science Solutions sales were particularly strong, climbing 9% due to strength in the Bioproduction, Biosciences and NGS businesses. Continued uptake for the new Ion S5 systems was driven by clinical oncology applications.

Analytical Technologies sales grew 3%, as sturdy growth for chromatography and MS products were partially hampered by weakness in the Chemical Analysis business. The company also highlighted strength in the acquired FEI Electron Microscopy business (see **IBO** 8/15/16) and emphasized order growth for structural biology applications.

Sales growth for the Laboratory Products and Services segment, which advanced 3%, slowed to more normal levels, as year-end spending was less pronounced compared to the previous year. Specialty Diagnostics revenue also grew 3%, with balanced growth across all businesses.

Geographically, Asia-Pacific sales grew roughly 12%, led by strong demand in China, India and South Korea. North America and European sales grew approximately 2% and 5%, respectively. Sales in Rest of World declined 2%.

Thermo Fisher's adjusted gross margin expanded 172 basis points to 49.4%. Adjusted operating margin advanced 154 basis points to 24.8%, including 40 basis points from fewer selling days. Productivity improvements and product mix further boosted operating profits, offsetting increased investments and dilution from acquisitions.

| Thermo Fisher Scientific FY16    |          |              |             |          |              |             |
|----------------------------------|----------|--------------|-------------|----------|--------------|-------------|
|                                  | Q4       |              |             | FY       |              |             |
|                                  | Rev. (M) | % Total Rev. | Org. Growth | Rev. (M) | % Total Rev. | Org. Growth |
| Life Sciences Solutions          | \$1,336  | 27.0%        | 5%          | \$4,978  | 27.2%        | 7%          |
| Analytical Technologies          | \$1,217  | 24.6%        | 2%          | \$3,668  | 20.1%        | 3%          |
| Specialty Diagnostics            | \$834    | 16.8%        | -2%         | \$3,339  | 18.3%        | 4%          |
| Laboratory Products and Services | \$1,757  | 35.5%        | -2%         | \$7,030  | 38.5%        | 5%          |

## 2016

Full-year 2016 sales grew 7.7%, 4.4% organically, to \$18.27 billion. Acquisitions contributed 4% to sales growth, while currency headwinds amounted to 1%. Biopharmaceutical sales climbed 10% to account for roughly 31% of revenues. Diagnostics and healthcare sales expanded 4% to represent 25%. Academic and government, and industrial and applied sales grew roughly 1% each to make up 25% and 19% of revenues, respectively. However, applied markets remained healthy with sales growth around 4%.

Life Science Solutions and Analytical Instrument sales grew 7% and 3%, respectively. Sales for the Laboratory Products and Services segment grew 5%. Specialty Diagnostics revenue advanced 4%.

Asia-Pacific sales grew 12% to make up 19% of revenues, led by high-teen sales growth in China. Sales in North

America and Europe improved 3% and 4% to account for 53% and 24% of revenues, respectively. Sales in Rest of World declined 4% to make up 4%.

For the year, adjusted gross margin improved 51 basis points to 48.8% and adjusted operating margin expanded 58 basis points to 23.1%.

Thermo Fisher projected 2017 sales to grow 6%-7%, 4% organically to \$19.38-\$19.62 billion. Acquisitions are expected to add 4% to sales growth, partially offset by projected currency headwinds of 1.5%. While demand from biopharmaceutical markets is expected to remain strong, sales growth for this market is anticipated to moderate compared to 2016 due to a strong comparison. The company projected biopharmaceutical sales to grow in the mid-to upper single digits. Industrial and applied revenue growth is expected to accelerate to roughly 4% in 2017, as stronger industrial orders should benefit growth in the second half of the year. Growth for the academic and government markets is expected to remain tepid, each with low single-digit growth. First quarter sales are expected to be slightly below the annual growth forecast due to one less selling day.

## Waters Offers Conservative Outlook

### Q4 2016

Waters posted fourth 2016 sales above company guidance due to sustained demand in Asia and accelerated growth in Europe. Organic sales advanced 8.6% to \$628.8 million, but benefited from delayed European orders in the third quarter of 2016 and roughly 4% growth from extra selling days. Based on normalized days, organic sales improved roughly 5% organically.

Following modest growth in the first nine months, sales in the industrial-related market, which includes materials characterization, food, environmental and fine chemicals, jumped 14%, its strongest quarter in three years. Demand was particularly strong for food quality and safety testing, as well as for fine chemical applications. Core industrial demand remained challenged.

Academic and government sales, which contracted 15% in the third quarter 2016, grew 6%, driven by increased adoption of the Vion Q-ToF MS system in both Europe and Asia. Biopharmaceutical sales also grew 6% but slowed compared to the first nine month of 2016. However, this pattern was similar to 2015 due to the absence of any meaningful budget flushes.

Within the Waters segment, instrument sales climbed 12%, including similar growth for LC and MS systems, and strong demand for laboratory informatics products. Recurring revenues advanced 9% but benefited from the extra selling days.

TA sales declined 3% due to a strong comparison and softer-than-expected instrument sales. However, TA sales and orders improved sequentially, driven by demand for the new Discovery thermal analyzer.

Geographically, sales in Asia Pacific excluding Japan grew 18%. Japanese sales advanced 6%.

European sales improved 9% due to strong instrumentation demand in Western Europe. Sales in the Americas grew 2%, as growth was partially hindered by weakness in industrial markets and slower demand from clinical diagnostics customers. Gross margin advanced 55 basis points to 60.0% of sales primarily due to favorable currency impacts. Adjusted operating profit improved 103 basis points to 34.1%.

| Waters FY16 |            |           |             |            |           |             |
|-------------|------------|-----------|-------------|------------|-----------|-------------|
|             | Q4         |           |             | FY         |           |             |
|             | Rev. (\$M) | % of Rev. | Org. Growth | Rev. (\$M) | % of Rev. | Org. Growth |
| Products    | \$442.8    | 70%       | 8%          | \$1,460.3  | 67%       | 9%          |
| Instruments | \$353      | 56%       | 9%          | \$1,114.9  | 51%       | 8%          |
| Consumables | \$90       | 14%       | 7%          | \$345.4    | 16%       | 9%          |
| Service     | \$186.0    | 30%       | 9%          | \$707.1    | 33%       | 11%         |

## 2016

Full-year 2016 Waters sales advanced roughly 6.5% organically to \$2.17 billion. Biopharmaceutical sales advanced just under 10%. Sales for the industrial category advanced nearly 6%, as strong demand for food testing products was partially offset by weakness in core industrial markets. Government and academic sales contracted 3% as a result of lower spending in Europe and the US.

Sales for the Waters segment expanded 7.3%, led by strong recurring revenues, which advanced 8%. Instrument sales grew 6.6%, with slightly stronger demand for LC systems, especially ACQUITY Arc and Alliance-based instrumentation. MS sales, which started on the slower side, benefited from demand for the ACQUITY QDa and Xevo tandem quadrupole systems. TA sales were flat, as instrument demand declined due to weakness in the materials science, polymer and metals markets.

Geographically, sales in Asia excluding Japan grew 12%, driven by biopharmaceutical demand in China and India. Japanese sales improved 4% due to strength from pharmaceutical and industrial customers. Sales in the Americas expanded 3%, including roughly 5% sales growth in pharmaceutical markets, flattish growth from industrial customers and lower growth in academic and government markets. European sales advanced 6%.

Total gross margin improved 13 basis points to 58.9% for the year. Adjusted operating income climbed 104 basis points to 30.1% because of improved efficiency and cost control measures.

For 2017, Waters projected a more conservative outlook, with organic sales growth in the mid-single digits. This forecast assumes biopharmaceutical and industrial sales to grow roughly 5% each, and low single digit sales growth in academic and government markets. First quarters organic sales are anticipated to rise 3%-5%, just below the annual average due to two fewer selling days.

| CY Q4 2016 Results       |            |               |          |                     |             |               |                       |          |  |
|--------------------------|------------|---------------|----------|---------------------|-------------|---------------|-----------------------|----------|--|
|                          | Revenues   |               |          | Rev. Growth Summary |             |               | Adj. Operating Profit |          |  |
|                          | Rev. (\$M) | % of Co. Rev. | % Growth | % Curr.             | % Acq./Div. | % Org. Growth | (\$M)                 | % Growth |  |
| Illumina                 | \$619.3    | 100%          | 4.7%     | 0%                  | 0%          | 5%            | \$155.6               | -3.8%    |  |
| PerkinElmer              | \$567.0    | 100%          | -0.5%    | -1%                 | 0%          | 1%            | \$120.6               | 2.2%     |  |
| Thermo Fisher Scientific | \$4,953.2  | 100%          | 6.5%     | -1%                 | 8%          | 0%            | \$1,227.1             | 13.5%    |  |
| Waters                   | \$628.8    | 100%          | 7.2%     | -2%                 | 0%          | 9%            | \$214.5               | 10.5%    |  |

## Cell Counters

Cell counters are tools for counting live and dead cells in a culture. Automated cell counters are an alternative to manual hemocytometer-based cell counting that offer more reliable and faster results. The hemocytometer, or counting chamber, was designed in 1874 by Louis Charles Malassez as the first instrument designed for cell counting. It consists of a thick glass microscope slide with a rectangular indentation that creates a gridded chamber where a sample is placed. Through a manual method of observation and counting, the number of cells in a sample is determined. Among the different reasons counting cells can be important are: ensuring you have enough cells to perform an experiment, identifying cell numbers that can affect the staining to perform an assay, measuring the magnitude of effects, and determining cell-loss for optimization of protocols.

There are two types of automated cell counters: image-based and electrical impedance-based systems (Coulter Counters). The former utilize brightfield or fluorescent microscopes coupled with CCD cameras to photograph the cells on the hemocytometer, and software to distinguish between and count live and dead cells. Similar to manual counting, many of these instruments use the trypan- or methylene-blue exclusion method to identify live cells.

On the contrary, electrical impedance-based systems cannot distinguish between live and dead cells (except by size), but only the number of cells present in the sample. These systems can also provide information regarding cell concentration and average cell size. In principle, as a cell passes through an orifice separating two chambers filled with an electrolyte solution, there is a change in electrical resistance. This resistance change is proportional to the

size of a cell. In this system, concentration of cells can be a problem, as the orifice can get clogged.

Beckman Coulter (Danaher) and Thermo Fisher Scientific combine to account for half of the cell counter market. Beckman Coulter's Vi-Cell product is based on the widely used trypan blue dye-exclusion method and features flow-through cell technology. Furthermore, Beckman Coulter's z-series Coulter counters are among the most widely used electrical impedance-based technologies. Thermo Fisher commercialize only image-based systems. In 2014, the company launched Countess II, which became a popular device in public and private research labs. The company is the leader in aftermarket supplies, such as slides and dyes.

In 2016, the market for cell counters totaled \$112 million and is expected to grow at a rate of more than 5% in 2017. Automated cell counters are time saving instruments that are gradually replacing traditional counting techniques with great success, which will be reflected in this year's growth rate.

### **Cell Counters at a Glance:**

#### *Leading vendors:*

- Beckman Coulter (Danaher)
- Life Technologies (Thermo Fisher Scientific)
- MilliporeSigma

#### *Largest markets:*

- Academia
- Hospital and Clinical
- Biotechnology

#### *Instrument cost:*

- \$2,000-\$55,000

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## **Clinical**

In January, the FDA released a discussion paper on laboratory-developed tests (LDTs), designed to compile the feedback it has received on its LDT draft guidance and to examine a possible approach to LDT oversight. This approach would include focused oversight addressing only "new and significantly modified high and moderate risk LDTs," excluding previously marketed LDTs. Oversight would be phased-in over four years. A new approach would broaden the definition of LDTs for "unmet needs," or tests for which no approved alternative is available. As for evidence standards, the paper describes how the proposed FDA and Centers for Medicare and Medicaid Services' reviews would not overlap. The FDA would expand its work with third-party premarket review programs and the clinical community, and evidence of a test's analytical and clinical validity would be made public. The FDA Quality System would also address the design and manufacture of LDT critical components, which are currently without oversight, assessing three aspects: design controls, acceptance activities, and corrective and preventive procedures.

Source: [FDA](#)

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## **Biotechnology**

The Trump administration's controversial decision to ban all travel from seven largely Muslim countries has resulted in opposition from the biotechnology industry. On February 7, in a letter published in *Nature Biotechnology*, almost 170 biotech executives stated that the ban was "poorly conceived and implemented," and that it is adversely affecting their companies. In the letter, executives cited a 2014 study that concluded that 52% of the 69,000 biomedical researchers in the US are immigrants, stating that it is largely due to the recruitment of foreign-born

researchers that the US biotech industry is as robust as it is. The letter declared that US biotech market is unique, not only due to the amount of capital that the country is able to pour into drug discovery, but also due to the varied national backgrounds of employees. The letter was signed by 166 biotech executives from private companies, venture capital firms and academia, including Daphne Zohar from PureTech Health, Gregory Flesher from OticPharma and Herve Hoppenot of Incyte.

Source: [Nature](#)

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## R&D

In a new data brief released earlier this month, the Organization for Economic Cooperation and Development (OECD) published updated R&D statistics detailing the stabilizing of R&D intensity in 2015. R&D intensity is defined as R&D expenditure as a percentage of a country's GDP. In OECD countries in 2015, R&D intensity plateaued at 2.4% and leveled at 1.95% in the EU area, driven largely by EU countries that invest the most in R&D (Germany with 2.9%, France with 2.2% and the UK with 1.7%). The leader in R&D intensity in 2013 and 2014 was Korea, but in 2015, Israel overtook Korea with a narrow lead in R&D intensity, at 4.25% compared to Korea's 4.23%. R&D intensity in the US increased nominally from 2.76% to 2.79% in 2015. China's R&D intensity also slightly increased in 2015, rising from 2.02% to 2.1%. Japan's R&D intensity declined from 3.59% to 3.49%.

In OECD countries, real business expenditure on R&D grew 2.3% in 2015, which is congruent with GDP increases. Government R&D expenditure increased 1.8%, with higher education institutes comprising 18% of R&D in OECD countries and government representing 11%. However, in real, purchasing power parity terms, government-financed R&D has dropped 2.4% since 2010, hitting a total of 27% in 2014 (or a total of 31% of total OECD R&D expenditure). The OECD's 2015 data on government-based R&D expenditure is mixed, indicating slight growth in OECD countries but declines in the US and Japan, two countries that, combined, represented 54% of OECD R&D expenditures in 2014 and 47% of government R&D expenditure in 2015.

In terms of government budgets or allocations of R&D in OECD countries, in 2015, these increased by 0.7%; accounting for inflation, however, government R&D budgets declined 0.2% in real terms. In 2016, data were also mixed, with the US data indicating growth in R&D budgets, but Japanese data indicating a decline and other OECD countries' data flat. In 9 out of the 16 countries for which OECD data are available, government-funded R&D budgets and allocations have declined. In 2014, an estimated 6.4% of business R&D came directly from government funds.

The data brief mentions the importance of tax incentives within the last few years, with 29 out of 35 OECD countries and other non-OECD members giving preferential tax rates for business R&D expenditures. Since 2006, government-supported tax relief has jumped from 37% to 45% in 2014 within OECD countries.

Source: [OECD](#)

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## South Korea

Earlier this month, the South Korean government announced a KRW 98.2 billion (\$82.76 million) investment into improving the evaluation guidelines for new biopharmaceutical products. The investment, implemented by the biotechnology committee led by the Ministry of Science, ICT and Future Planning, covers new biopharmaceutical products over the course of the next 10 years.

As part of the committee's outline, the Ministry of Food and Drug Safety will allocate KRW 40 billion from 2017 to 2027 for the purpose of improving the regulatory guidelines for stem cell therapies. The Ministry will also invest KRW 20 billion into precision medicine and allocate KRW 38 million for vaccines for infectious diseases. Additionally, the Ministry also plans to devise regulatory standards for next generation biologics.

In a statement, the Ministry explained that the measures the country has taken to improve its biopharmaceutical

industry fall short of ensuring Korea's position as a global leader in the industry. To remedy this, the Ministry announced plans to establish agreements with overseas drug regulators that recognize the respective countries' GMP certification to increase and strengthen South Korea's presence in the industry. Currently, South Korea accounts for approximately 1% of the global biopharmaceutical market and is 14<sup>th</sup> in market size. The committee also stated that it plans to fund projects beyond strictly medicine-based biopharmaceutical R&D, and will also encompass industrial-focused and plant-based biotechnology.

The Ministry of Science also announced its agenda to streamline R&D funding for DNA therapy, genomics, precision medicine and disease diagnostics technologies by merging the sectors into a single government agency.

Source: [The Korea Herald](#)

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## Brazil

After months of tension between the government and domestic scientists due to major cuts in science funding (see [IBO 10/31/2016](#) and [IBO 6/15/2016](#)), in January, the Brazilian government reverted back to the original \$527 million budget for the Ministry of Science, Technology, Innovation and Communications. The Brazilian Society for the Advancement of Science (SBPC) and the Brazilian Academy of Sciences created a petition protesting the funding cuts when they were first announced, obtaining the support of nine other science agencies and 26,000 signatures. Helena Nader, president of the SBPC, explained that the strain between scientists and the government had been sparked with the government's decision to cap academic government spending for 20 years.

The restoration is effective immediately, with the restored funds going towards paying the Ministry's administration costs, as well as science scholarships for January and February.

Source: [Agência Brasil](#)

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## India

On February 1, the Indian government released the country's Union Budget for 2017-2018. Science received a slight boost in government funding, with biotechnology and renewable energy in particular receiving significant increases.

The Department of Science and Technology (DST) was allocated INR 4,817.27 crore (\$710.4 million = \$1 = INR 67.66), with INR 2,310.90 crore (\$342.1 million) for funding of "Central Sector Schemes and Projects." This category includes the DST's budget for R&D, which received funding of INR 595.50 crore (\$87.8 million), as well as technology innovation, development and deployment, which was allotted INR 651.90 crore (\$96.1 million). The DST'S total budget for 2017-2018 is an increase of 7.8% from last year's, with funding for "Central Schemes and Projects" rising 10.8% this year.

A major winner in the budget bill is the Ministry of New and Renewable Energy, which has been allocated INR 5,472.84 crore (\$807.1 million), a 25.5% boost. Funding for the Department of Biotechnology also augmented, accounting for INR 2222.11 crore (\$327.7 million) in the 2017-2018 budget, a 15.9% increase. With allocations rising 23.5% in this year's budget, the Department of Health and Family Welfare received INR 47,352.51 crore (\$7.0 billion), while funding for the Department of Health Research increased 11.5% to INR 1,500.00 crore (\$221.2 million). The Ministry of Food Processing Industries was allocated INR 800.00 crore (\$118.0 million), a 9.7% jump from last year.

Source: [Ministry of Finance, Government of India](#)

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# Europe

In a new report entitled “Pharmaceutical Innovation in Europe,” EvaluatePharma analyzed the impact of new medicinal breakthroughs in the pharmaceutical industry in Europe, forecasting the product levels for 300 in-line and over 500 pipeline assets until 2022. The report indicates that the pharmaceutical industry is poised to grow at a CAGR of 3.2% for the eight-year period of 2015 to 2022, while GDP is forecast to grow 1.6% per year. Due to the launch of various initiatives to develop medicines that focus on unmet medical issues, such as the Priority Medicine initiative, a trend has emerged of greater collaboration between EU regulators and pharmaceutical manufacturers.

The oncology market is estimated to grow at a CAGR of 8% from 2015 to 2022, while the diabetes market is forecast to grow at a CAGR of 5%. New biosimilar therapies have affected the immunology market, which is expected to decline at a CAGR of 3% over the eight-year period. The report calls for EU regulators and payers to work with pharmaceutical companies to develop more efficient funding mechanisms to put in place of the current pay-for-performance scheme, as the latter is proving to be unsustainable in the long term.

Source: [EvaluatePharma](#)

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## Atomic Spectroscopy

### Company Announcements

In December 2016, **Applied Spectra**, a provider of LIBS and laser ablation technologies, named Executive Vice President Dr. Jong H. Yoo as president and CEO. He replaces Dr. Richard E. Russo, who will serve as executive chairman.

**Tribogenics** announced in January a distribution agreement with **HORIBA Scientific** for Southeast Asia.

### Product Introduction

In fall 2016, **Belec Spektrometrie Opto-Elektronik** introduced the redesigned Belec Vario Lab, featuring lower argon consumption and a more powerful plasma generator.

**Bruker AXS** launched in November 2016 the D8 ADVANCE PLUS XRD solution, featuring the new TRIO OPTIC, with motorized switching between the three primary beam geometries and fully software-controlled instrument alignment.

In January, **SPECTRO Analytical Instruments** introduced the SPECTROPORT portable arc/spark OES metals analyzer, stating it is as fast as handheld XRF but can accurately analyze elements that portable XRF cannot, such as carbon and sulfur. It includes transport trolleys and a cordless, rechargeable battery pack.

**PerkinElmer** launched in January the NexION 2000 ICP-MS, stating it is designed “to handle any sample matrix, address any interference and detect any particle size.” It is the only ICP-MS that can run pure highly reactive gases, such as ammonia, and features a choice of three gas channels.

In January, **Oxford Instruments** released the handheld Vulcan LIBS analyzer, designed for the rapid identification of a wide range of alloys in manufacturing plants within multiple industries and the scrap metal processing/recycling markets. It takes one second to measure metal alloys. It is connected to the OiConnect cloud service.

**Shimadzu** released in January the EDXIR-Analyses software package for contaminant analyses and confirmation tests, calling it the first EDX-FTIR contaminant find/material inspector. It integrates data from EDX and FT-IR instruments.

In February, **Xenometrix** launched the P-Metrix, a battery-powered, portable ED-XRF system that weighs 32 lb (14.5 kg). It features automated self-calibration.

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# Sample Preparation

## Company Announcements

In February, **Pressure BioSciences** announced CE marking for its Barocycler 2320EXTREME.

## Product Introductions

**Promega** launched in fall 2016 the Maxwell RSC GMO and Authentication Kit for food testing. It provides efficient purification of DNA for use in PCR-based testing for GMO DNA sequences, and PCR-based food and ingredient authentication. It utilizes paramagnetic particles and works with target material from 1 to 16 samples.

**MO BIO Laboratories** (now **QIAGEN**) introduced last fall the AllPrep Bacterial and Fungal DNA/RNA/Protein Kits, which utilizes a spin filter format and a bead beating method.

In fall 2016, **S-BIO**, a division of **Sumitomo Bakelite**, launched the EZGlyco mAb-Kit with 2-AB for analyzing N-glycans in IgG and Fc-fusion proteins from culture supernatant samples in a rapid, simplified and streamlined single tube operation.

In fall 2016, **Innova Biosciences** released the AbPure Magnetic Purification system based on Protein A Magnetic Beads to facilitate the production of conjugates.

**Chromatrap**, a **Porvair** business, released in fall 2016 the filter-based FFPE ChIP Kit, available in 96-well or spin column formats.

**Beckman Coulter Life Sciences** introduced in fall 2016 the FormaPure DNA, a FFPE DNA extraction kit, featuring reduced turnaround times and less than 15 minutes of hands-on time when automated with the Biomek liquid handler. Sold in three kit sizes, it is currently available in North America.

In November 2016, **Zymo Research** introduced: the ZymoPURE Plasmid Miniprep Kit, which yields up to 80 µg of ultra-pure and highly concentrated plasmid DNA; the ZymoPURE-EndoZero Kit, which yields up to 3 µg/µL highly concentrated plasmid DNA; and the ZymoPURE-Express Plasmid Midiprep Kit, which isolates endotoxin-free plasmid DNA directly from culture in only 15 minutes.

**Restek** introduced in December 2016 improved SPE cartridges that completely separate aliphatic and aromatic compounds into distinct fractions.

In December 2016, **Porvair Sciences** introduced the 96-well Seed Genomics plates for high-throughput plant genomic sample preparation. They withstand demanding applications using steel ball bearings in wells shaken at up to 1,500 rpm.

**Creative Diagnostics** released in January new magnetic beads as part of its Absolute Mag platform.

In February, **Sage Science** introduced the SageHLS platform for extracting and purifying extremely large DNA fragments directly from bacterial and tissue cultures, blood samples or other cell sources. It can purify DNA into fragments ranging from 50 kb to 2 mb.

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# Materials Characterization

## Company Announcements

In fall 2016, **TA Instruments** announced a partnership with the **National Elastomer Center at Ferris State University**.

**NETZSCH** announced in fall 2016 a collaborative sales partnership with **Alpha Technologies** to serve the rubber and polymer industry.

**HORIBA** announced in November 2016 the opening the 7,066 m<sup>2</sup> (76,058 ft<sup>2</sup>) HORIBA India Technical Center in Pune, India, which includes a showroom for materials analysis instruments. Housing 45 employees, the Center focuses on the country's growing auto industry.

In its third quarter 2016 **SEC** filing, **Waters** disclosed a purchase price of \$6 million in cash for **Rubotherm** (see **IBO** 9/15/16).

In December 2016, **Elektron Technologies** completed the sale of its **Wallace Instruments** business, a provider of rubber testing instruments, to C&M Projects, for £1.3 million (\$1.4 million). Wallace recorded sales of £1.2 million (\$1.8 million) for the year ending January 2016.

In January, **MTS Systems** appointed Maximiliane Straub to its Board. She is currently CFO and executive vice president, Finance, Controlling and Administration, at **Robert Bosch**.

## Product Introductions

In fall 2016, **NETZSCH** introduced the GABO EPLEXOR modular instrument for thermal-mechanical characterization for testing of materials under real-life conditions in the ultra-high-force range. It features the MPAS automatic sample changer.

**Thermo Fisher Scientific** launched in fall 2016 the HAAKE Minilab micro-compounder, used to measure structural changes during compounding and assess rheological properties of test materials for R&D.

In fall 2016, **Microtrac** released the Nanotracs Wave II dynamic light scattering analyzer, which is ideal for colloids ranging in size from 0.3 nm to 10 µm. It features sample introduction flexibility and works with sample volumes of 50 µL microcuvettes to 3 mL cells.

**BYK-Gardner** introduced in December 2016 the byko-visc rotational viscometers, consisting of low-, medium- and high-viscosity system. They feature user calibration and a Quick Disconnect accessory. Also released was the byko-visc DS, a Stormer-type viscometer primarily designed for the paint and coating industries.

In December 2016, **Proceq** released Equotip Live, calling it the first full Internet of Things/Industry 4.0 portable hardness testing solution. No cables are required.

**TA Instruments**, a **Waters** company, introduced the new TAM Air Microcalorimeter for the characterization of the heat of hydration of cement and for emerging applications. It features new performance specifications.

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# Nucleic Acid Amplification

## Company Announcements

In fall 2016, **Meridian Bioscience** amended its license agreement with **Eiken Chemical** for its LAMP (Loop-mediated Isothermal Amplification) technology to include molecular detection of infectious agents in animals, food and water.

**Transgenomic** announced in fall 2016 distribution agreements with **JoyingBio** for China and **Biotron Healthcare** for India for its ICE COLD-PCR technology.

In October 2016, **Canon BioMedical** named **Labtech** as a distributor for its Novallele genotyping products in the UK and Ireland.

**JN Medsys** entered into a distribution agreement in October 2016 with **LMS** for Japanese distribution of its Clarity digital PCR system.

In October 2016, **SYGNIS** announced the receipt of a three-year, £1.2 million (\$1.3 million) soft loan from Spain's **RETOS program** as part of a collaboration with the **Spanish National Center for Molecular Biology, San Carlos Hospital** and **Juan Dominguez**, an R&D foundation.

## Product Announcements

**Bioline**, a **Meridian Bioscience** subsidiary, launched in fall 2016 the SensiFAST Lyo-Ready No-ROX Mix, a ready-to-use, lyophilization-compatible qPCR mix.

In January 2017, **Bioline**, in collaboration with **MiRXES**, expanded its EPIK miRNA Select Assays to include all organisms listed on the miRBase release 21.

In fall 2016, **InnoGenomics Technologies** released new kits for analyzing challenging forensic samples: the InnoTyper 21 DNA typing system for obtaining results from challenging and degraded samples, and the Innotype HY quantitative assay for comprehensive sample assessment and increased downstream DNA profile recovery. They feature the use of retrotransposable elements, which are noncoding genomic DNA repeat sequences.

In fall 2016, **DiaCarta** released the QFusion RT-qPCR assay for the detection of ALK fusion gene variants. The single tube, multiplexed reactions require 50 ng of RNA from FFPE samples and take around one-and-a-half hours. According to the company, it is the only commercial qPCR kit that detects both EML4-ALK and KIF5B-ALK fusion gene variants.

**Bibby Scientific's** (now **Cole-Parmer**) **PCRmax** business launched in fall 2016 the Alpha Cyclor 2, a compact, dual block system, featuring a remote monitoring system.

In fall 2016, **SYGNIS** released the end-point PCR-based, 96-well-format CovCheck kit for the QC of whole-genome amplification coverage. It enables the evaluation of the genomic coverage of four independent single-cell whole-genome-amplification experiments simultaneously.

In January, **LGC** introduced the Hydrocycler<sup>2</sup> next generation water bath thermal cycler, which allows labs to process more than 145,000 samples in an eight-hour day. Compared to the previous system, it features a smaller footprint, reduced setup costs and easier service.

**Thermo Fisher Scientific** launched in fall 2016 the Applied Biosystems NGM Detect PCR Amplification Kit, powered by six-dye chemistry, for maximizing information recovery from degraded samples.

In November 2016, **Integrated DNA Technologies** introduced PrimeTime Gene Expression Master Mix for probe-based qPCR assays. It is stable for ambient shipping.

**Promega** released in November 2016 the Promega PCR Optimization Kit, which allows customers to rapidly define their own unique PCR master mix manufactured under cGMP for research or clinical use. The Kit includes magnesium chloride, GoTaq MDx Hot Start Polymerase and eight PCR buffers. It ships within 10 business days.

In November 2016, **RainDance Technologies** (now **Bio-Rad Laboratories**) launched the RainDrop *Plus* Digital PCR System, featuring faster droplet detection, higher throughput and new automated analysis capabilities.

**3M** released in November 2016 the 3M Molecular Detection Assay 2—Cronobacter, a bacterium that has been associated with contaminated powdered infant formula.

In December 2016, **New England Biolabs** introduced the Luna Universal qPCR & RT qPCR kits, optimized for DNA and RNA quantitation from diverse sample sources and target types. Its reference dye universally supports real-time instruments and a blue visible dye assists in tracking the reagents when pipetted.

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# Bioprocess Analysis

## Company Announcements

**IDA Ireland** announced in fall 2016 that **GE Healthcare** will build GE BioPark Cork, a €150 million (\$195 million) biopharmaceutical manufacturing campus in Cork, Ireland. In addition, the **National Institute for Bioprocessing Research and Training-GE** Single-use Centre of Excellence will be formed to train bioprocessing professionals.

**GE Healthcare Life Sciences** announced in fall 2016 the opening of a \$7.4 million, 2,200 m<sup>2</sup> (23,681 ft<sup>2</sup>) GE Fast Trak Center in Sondo, South Korea, which will provide training, technology evaluation, manufacturing support and consultancy services.

In November 2016, **GE Healthcare Life Sciences** announced a \$7 million expansion of its single-use technology manufacturing facility in Westborough, Massachusetts. It will manufacture a range of products, including cell growth bag, based on a newly developed film platform resulting from GE's strategic alliance with **Sealed Air**. The company also announced the establishment of an enlarged extractables and leachables analytical lab in Uppsala, Sweden.

In fall 2016, **Pall** signed a collaboration agreement with **RoosterBio** an adult stem cell technology company, to codevelop and market complete solutions for industrial-scale bioreactor expansion of hMSCs.

In January, **MilliporeSigma** opened two new process development centers near Boston in the US and near Shanghai in China. The centers provide the full range of process development capabilities and services.

In February, **INFORS HT** opened its 27,000 ft<sup>2</sup> (2,508 m<sup>2</sup>) US headquarters in Annapolis Junction, Maryland.

## Product Introductions

**INFORS HT** launched in fall 2016 the eve bioprocess platform software for planning, implementation, control and evaluation of complex experiments. It is tailored for applications in shakers and bioreactors. The core software and the first package, Plan & Control, are available. In January, a second package, "User Management & Reporting" for performing validation processes, was launched.

In fall 2016, **INFORS HT** introduced the Minifors 2 benchtop bioreactor, featuring two mass flow controllers, four pumps, and digital pH and pO<sub>2</sub> sensors. The culture vessel is available in three sizes.

**Pall Life Sciences** released in fall 2016 the Cadence BioSMB Process system single-use flow path, continuous multi-column chromatography system, designed for use with feedstreams derived from fed batch bioreactions of up to 2,000 L volume. It can operate with up to eight chromatography columns.

In fall 2016, **Finesse Solutions** introduced the 15 L vessels for its SmartGlass autoclavable glass bioreactors, which now offers a choice of 1 L, 3 L, 7 L and 15 L total volume.

**Finesse Solutions** launched in November 2016 the SmartVessel, a single-use 3 L bioreactor vessel, featuring integrated single-use sensors.

In December 2016, **Finesse Solutions** released the new G3Lite+ SmartController for upstream cell culture and fermentation. It is now available for the Mobius CellReady, Thermo Scientific HyPerforma TK SUB, the GE Xcellerex XRF and the Pall PadReactor single-use vessels.

**Resolution Spectra System** introduced in November 2016 the ProCellics bioprocess Raman solution for inline monitoring of metabolites and nutrients during upstream processes.

In January, **Eppendorf** launched the BioFlo 120 benchscale fermentor/bioreactor system for R&D. It features a range of glass and BioBLU Single-Use Vessel options (250 mL–40 L). It features a new Auto Culture mode for push

button control.

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## Process Analysis

### Company Announcements

In November 2016, **Teledyne Technologies** announced an agreement to purchase **IN USA**, a manufacturer of ozone generators, ozone analyzers and other gas monitoring instrument based on UV and IR technologies. The company joins **Teledyne Advanced Pollution Instrumentation**.

In December 2016, **Yokogawa Electric** and **Gazprom Neft** agreed to establish an International Center for Innovation in St. Petersburg, Russia, to develop advanced process control systems and other solutions for Gazprom's refineries.

In 2016, sales for **MKS Instruments Analytical Solutions Products** declined 1.7% to \$60.7 million, or 7% of company revenues (see [Bottom Line](#)).

### Product Introductions

In November 2016, **Hidden Analytical** launched the Hiden HPR-40 DSA MS system for measurement of gases and vapors in aqueous media. It features a fine membrane for significant enrichment of gaseous throughput relative to that of water vapor. Interface types include insertion probes, flow-through patterns, cuvette styles and DEMS cells.

**MKS Instruments** released in November 2016 Easy Analytics, part of its Umetrics Suite of Data Analytics Solutions. A stand-alone solution, it imports, organizes, and analyzes process and quality data.

In November 2016, **IONICON** introduced the small and lightweight PTR-TOFMS system, with a detection limit down to 5 pptv, for trace VOC analysis.

In December 2016, **PAC**, a **Roper Technologies** company, released the NSure sulfur and nitrogen analyzers, based on Antek UVF spectrometry, for real-time monitoring and process control.

**DKK-TOA** introduced in December 2016 a new range of pH/ORP meters, featuring a two-point calibration diagnosis.

In January, **AGC Instruments** launched the NovaAIR GC range of instruments, beginning with the NovaAIR 3000 system for methane/non-methane hydrocarbon analysis, including ambient air monitoring.

**Anton Paar** released in January the Oxy 510 inline sensor for beverage production. Measurements can be taken in both the trace range (0-2,000 ppb) and the wide range (0-22.5 ppb).

In February, **Anton Paar** launched the Litesizer 100 particle analyzer for determining particle size, transmittance, molecular mass and second viral coefficient. It features a one-page workflow.

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## Reported Financial Results

| \$US   | Period | Ended  | Sales     | Chg.   | Op. Prof. | Chg.     | Net Prof. | Chg.     |
|--|--------|--------|-----------|--------|-----------|----------|-----------|----------|
| Agilent Technologies                         | Q1     | 31-Jan | \$1,067.0 | 3.8%   | \$206.0   | 32.9%    | \$168.0   | 38.8%    |
| Agilent Tech. (Life Sciences & Applied)      | Q1     | 31-Jan | \$540.0   | 2.7%   | \$126.0   | 10.5%    | NA        | NA       |
| Agilent Tech. (Diagnostics & Genomics)       | Q1     | 31-Jan | \$164.0   | 3.8%   | \$23.0    | 53.3%    | NA        | NA       |
| Agilent Tech. (Agilent CrossLab)             | Q1     | 31-Jan | \$363.0   | 5.5%   | \$74.0    | -2.6%    | NA        | NA       |
| AMETEK                                       | Q4     | 31-Dec | \$973.0   | -1.5%  | \$173.2   | -17.1%   | \$109.1   | -20.3%   |
| AMETEK (Electronic Instruments)              | Q4     | 31-Dec | \$616.0   | -2.0%  | \$141.1   | -12.7%   | NA        | NA       |
| AMETEK                                       | FYE    | 31-Dec | \$3,840.1 | -3.4%  | \$801.9   | -11.7%   | \$512.2   | -13.3%   |
| AMETEK (Electronic Instruments)              | FYE    | 31-Dec | \$2,360.3 | -2.4%  | \$577.7   | -9.6%    | NA        | NA       |
| Becton, Dickinson                            | Q1     | 31-Dec | \$2,922.0 | -2.1%  | \$811.0   | 130.4%   | \$562.0   | 145.4%   |
| Becton, Dickinson (Life Sciences)            | Q1     | 31-Dec | \$958.0   | 2.7%   | \$198.0   | -2.0%    | NA        | NA       |
| Bio-Techne                                   | Q2     | 31-Dec | \$131.8   | 9.0%   | \$16.1    | -55.2%   | \$6.3     | -75.6%   |
| Bio-Techne (Biotechnology)                   | Q2     | 31-Dec | \$86.0    | 13.3%  | \$39.5    | -1.3%    | NA        | NA       |
| Bio-Techne (Protein Platforms)               | Q2     | 31-Dec | \$21.5    | 11.4%  | \$1.8     | 20.6%    | NA        | NA       |
| Bruker                                       | Q4     | 31-Dec | \$470.3   | -1.7%  | \$76.9    | 8.8%     | \$69.0    | 12.4%    |
| Bruker (Scientific Instruments)              | Q4     | 31-Dec | \$435.0   | -0.9%  | \$73.6    | 13.2%    | NA        | NA       |
| Bruker (Energy & Supercon Technologies)      | Q4     | 31-Dec | \$39.0    | -8.2%  | \$2.6     | -51.9%   | NA        | NA       |
| Bruker                                       | FYE    | 31-Dec | \$1,611.3 | -0.8%  | \$177.2   | 21.6%    | \$153.6   | 51.2%    |
| Bruker (Scientific Instruments)              | FYE    | 31-Dec | \$1,492.6 | -0.4%  | \$168.9   | 26.8%    | NA        | NA       |
| Bruker (Energy & Supercon Technologies)      | FYE    | 31-Dec | \$130.2   | -2.6%  | \$6.7     | -41.7%   | NA        | NA       |
| Fluidigm                                     | Q4     | 31-Dec | \$25.1    | -18.4% | (\$17.7)  | -29.3%   | (\$17.7)  | -37.4%   |
| Fluidigm                                     | FYE    | 31-Dec | \$104.4   | -8.9%  | (\$73.2)  | -45.9%   | (\$76.0)  | -42.5%   |
| Luminex                                      | Q4     | 31-Dec | \$72.3    | 19.6%  | (\$2.3)   | NM       | (\$3.4)   | NM       |
| Luminex                                      | FYE    | 31-Dec | \$270.6   | 13.9%  | \$21.0    | -43.8%   | \$13.8    | -62.5%   |
| Mettler-Toledo International                 | Q4     | 31-Dec | \$709.7   | 5.4%   | \$188.7   | 12.1%    | \$137.8   | 11.7%    |
| Mettler-Toledo International                 | FYE    | 31-Dec | \$2,508.3 | 4.7%   | \$540.7   | 10.3%    | \$384.4   | 8.9%     |
| MKS Instruments                              | Q4     | 31-Dec | \$405.1   | 135.0% | \$62.5    | 181.5%   | \$45.5    | 78.2%    |
| MKS Instruments                              | Q4     | 31-Dec | \$1,295.3 | 59.2%  | \$157.3   | 0.4%     | \$104.8   | -14.3%   |
| Pacific Biosciences                          | Q4     | 31-Dec | \$25.7    | -29.1% | (\$17.9)  | -1583.1% | (\$19.0)  | -1250.6% |
| Pacific Biosciences                          | FYE    | 31-Dec | \$90.7    | -2.2%  | (\$71.2)  | -144.5%  | (\$74.4)  | -134.7%  |
| PerkinElmer                                  | Q4     | 1-Jan  | \$566.8   | -0.5%  | \$80.4    | 4.2%     | \$64.8    | -5.0%    |
| PerkinElmer (Discovery & Analytical Solution | Q4     | 1-Jan  | \$409.9   | -2.0%  | \$72.0    | 11.8%    | NA        | NA       |
| PerkinElmer (Diagnostics)                    | Q4     | 1-Jan  | \$156.8   | 3.4%   | \$34.0    | -8.0%    | NA        | NA       |
| PerkinElmer                                  | FYE    | 1-Jan  | \$2,115.5 | 0.5%   | \$283.1   | 12.8%    | \$234.3   | 10.3%    |
| PerkinElmer (Discovery & Analytical Solution | FYE    | 1-Jan  | \$1,513.0 | -1.0%  | \$207.5   | 19.5%    | NA        | NA       |
| PerkinElmer (Diagnostics)                    | FYE    | 1-Jan  | \$602.5   | 4.5%   | \$138.9   | 2.5%     | NA        | NA       |
| QIAGEN                                       | Q4     | 31-Dec | \$366.5   | 5.2%   | \$4.2     | -92.7%   | \$8.6     | -83.0%   |
| QIAGEN                                       | FYE    | 31-Dec | \$1,338.0 | 4.5%   | \$98.8    | -44.9%   | \$80.4    | -38.2%   |
| Other Currencies                             |        |        |           |        |           |          |           |          |
| Biotage                                      | Q4     | 31-Dec | SEK 179.1 | 6.3%   | SEK 24.1  | 19.5%    | SEK 17.5  | -15.6%   |
| Biotage                                      | FYE    | 31-Dec | SEK 385.8 | -36.8% | SEK 99.1  | 32.5%    | SEK 92.8  | 26.7%    |
| HORIBA                                       | Q4     | 31-Dec | ¥53,191   | 3.2%   | ¥7,840    | 25.4%    | ¥5,680    | 24.0%    |
| HORIBA (Process & Environmental)             | Q4     | 31-Dec | ¥4,943    | 2.9%   | ¥418      | -29.5%   | NA        | NA       |
| HORIBA (Scientific)                          | Q4     | 31-Dec | ¥7,609    | 1.2%   | ¥841      | 51.0%    | NA        | NA       |
| HORIBA                                       | FYE    | 31-Dec | ¥170,093  | -1.1%  | ¥18,499   | -8.2%    | ¥12,962   | -2.4%    |
| HORIBA (Process & Environmental)             | FYE    | 31-Dec | ¥16,753   | 0.3%   | ¥1,756    | 14.0%    | NA        | NA       |
| HORIBA (Scientific)                          | FYE    | 31-Dec | ¥25,738   | -3.8%  | ¥944      | -21.1%   | NA        | NA       |
| Shimadzu                                     | Q3     | 31-Dec | ¥81,558   | 0.9%   | ¥6,699    | -14.0%   | ¥5,499    | 10.6%    |
| Shimadzu (Analy. & Meas. Instr.)             | Q3     | 31-Dec | ¥50,721   | 0.4%   | ¥6,571    | -10.5%   | NA        | NA       |
| Spectris                                     | FYE    | 31-Dec | £1,345.8  | 13.1%  | £38.3     | -73.3%   | £10.3     | -90.9%   |
| Spectris (Materials Analysis)                | FYE    | 31-Dec | £418.9    | 15.0%  | £66.2     | 55.4%    | NA        | NA       |
| Takara Bio                                   | Q3     | 31-Dec | ¥7,446    | 0.0%   | ¥1,347    | 77.2%    | ¥894.0    | 91.0%    |

*N/A=not available, NM=not meaningful*  
*Click to enlarge*

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