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Medicare Gives Green Light to NGS IVDs

In what is viewed as a step forward for NGS-based clinical testing, the US Centers for Medicare & Medicaid Services (CMS) announced this month a final National Coverage Determination (NCD) for FDA-approved NGS tests

for advanced cancer (defined as either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV) patients as long as certain criteria are met. An NCD decides what services will be paid for by the government's national Medicare program. Medicare covers roughly 15% of the US population, according to AARP. The NCD was specifically issued for Foundation Medicine's FoundationOne CDx (Companion Diagnostics) test for solid tumors.

With the CMS' first reimbursement approval of an NGS IVD test, and the policy it appears to set, NGS diagnostic testing overcomes another barrier to routine use. Also, the NCD builds upon the momentum created by a number of FDA-approval "firsts" for NGS IVDs over the last year and a half (see table below). NGS CDx tests have been pioneers in this regard. In total, of the 5 FDA-approved NGS tests, 4 are CDx tests. The approvals also suggest the FDA's growing regulatory acceptance of the single test–multiple drug and single test–multiple determination models enabled by NGS, in addition to the traditional single test–single drug model for CDx.

Test	FDA 'First'	Date of FDA Approval	Biomarkers	Number of Genes	Indications	Number of Therapies
Foundation Medicine's FoundationFocus CDxBRCA	First FDA-approved NGS CDx	December 2016	BRCA1 and BRCA2 alterations	2	Ovarian cancer	1
Illumina's Extended RAS Panel	First FDA-approved NGS CDx using an negative detection status, and first for evaluating RAS mutations in colorectal cancer to determine patient eligibility for treatment with Vectibix	June 2017	Mutations in KRAS and NRAS genes	2	Colorectal cancer	1
Thermo Fisher Scientific's Oncomine Dx Target Test	First FDA-approved NGS CDx for mulltiple indications	June 2017	Single nucleotide variants, deletions	23	Non–small cell lung cancer	4
Foundation Medicine's FoundationOne CDx	First FDA-approved NGS CDx test for detecting multiple mutations in all solid tumors	November 2017	Substitutions, indels, copy number alterations, microsatellite instability, tumor mutational burden	324	All solid tumors	15

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The NCD is also important, according to commentators, in that it revises an earlier draft that had put greater restrictions on coverage, and thus it allays some concerns about the CMS' approach particularly in regard to local Medicare (private contractors that process Medicare claims) coverage and disease criteria for coverage. As R. Bruce Williams, MD, FCAP, president of the College of American Pathologists, put it in a press release, "While the final NCD nationally covers only approved or US Food and Drug Administration (FDA)–cleared tests using NGS, the final determination leaves the local Medicare Administrative Contractor with the discretion to cover all other tests as long as specific patient criteria are met. The expanded criteria include recurrent, relapsed, refractory, metastatic, and advanced stages III or stages IV of cancer."

Impact?

However, the NCD's ultimate impact on FDA-approved NGS tests is still uncertain. "It is too early to say what effect the NCD will have on adoption of FDA-approved NGS tests," said Richard L. Schilsky, MD, FACP, FASCO, FSCT, chief medical officer of the American Society of Clinical Oncology (ASCO). "In general, ASCO supports regulatory oversight of these complex tests, but appropriate oversight should not impede access to medically appropriate NGS testing."

For FDA-approved NGS CDx test and sequencer manufacturers Illumina and Thermo Fisher Scientific, the NCD was well received. Joydeep Goswami, PhD, president of Clinical Next Generation Sequencing and Oncology for Thermo Fisher thinks the NCD will positively impact NGS IVD testing in general. "We expect this CMS decision to encourage the development of more NGS-based tests and greater adoption of these tests by labs to help patients," he said. "We are also hopeful that the FDA will continue to streamline requirements to help these tests to get to market faster and more cost effectively."

Illumina also greeted the NCD announcement with enthusiasm, highlighting the implications for CMS reimbursement for all FDA-approved NGS IVDs. "[B]ased on the language in the final NCD, coverage for FDA-approved, NGS-based, CDx assays in advanced cancers will be automatic in the future," said Garrett Hampton, PhD, executive vice president, Clinical Genomics, at Illumina. "Thus, this decision opens up a clear pathway for reimbursement of CDx assays that identify patients for novel targeted therapies, as well as for CDx assays measuring tumor mutational burden for Immuno-Oncology (IO) indications, and combinations of targeted therapies with IO therapies." In addition to CDx for standard treatments, the FoundationOne CDx test also includes biomarkers for targeted oncology therapies, such as IO. "This NCD comes at a time when the market is poised to leverage gene panel sequencing to support emerging targeted and IO therapies," said Dr. Hampton.

The NCS is especially significant to both companies as each are working to establish their newly FDA-approved NGS IVDs and roll out future such tests. Illumina's Extended RAS CDx panel for metastatic colorectal cancer, which gained FDA approval and was launched last year, is the company's first PreMarket Approval (PMA) and first CDx test. Illumina's NGS test previously approved by the FDA was approved under 510(k) clearance, a less rigorous standard than PMA as it only requires substantial equivalence to a previously approved device.

The Extended RAS Panel is also important as a product an FDA-approved NGS LDT, according to Dr. Hampton. "Notably, a key aspect of the Illumina NGS-based CDx test is that the Extended RAS Panel on the MiSeqDx System enables labs to implement an in-house solution for precision oncology, and signifies that NGS has reached a milestone as a clinical diagnostic platform to aid therapeutic decision-making in oncology," he told ***IBO***. Foundation Medicine's test must be performed at its own labs. Illumina continues to develop NGS CDx tests and has publicly announced partnerships with drug makers Amgen, AstraZeneca, and Merck Serono for NGS CDx development.

Illumina's plans include eventual FDA-approval of its TruSight panels, which are currently available as RUO panels, each using multiple markers to test for specific disease types. Illumina's RUO TruSight Tumor 170 test includes biomarkers for effectiveness of IO treatments. "At JP Morgan this year, we announced our intention to extend the TruSight menu to include a 500-gene panel, which we intend to bring to market as an IVD long term to assess tumor mutation burden for stratification of checkpoint inhibitors," explained Dr. Hampton.

For Thermo Fisher Scientific, which is developing additional indications for its FDA-approved Oncomine Dx Target Test for CDx, the first NGS-based test to receive FDA approval for Non-Small Cell Lung Cancer (NSCLC), the NCD guarantees CMS reimbursement for future extensions of the test. "Given that CMS had determined to cover NGS tests that are approved by FDA, expansion of the Oncomine Dx Target Test with additional genes/markers for other indications/drugs in cancer would automatically be covered by CMS once these have received FDA approval via a supplemental PMA," explained Dr. Goswami.

In addition, it affects CDx tests yet to be introduced by the company. Last year, Thermo Fisher announced agreements with Argios Pharmaceuticals to develop a Oncomine-based CDx for markers of advanced IDH1m positive cholangiocarcinoma (bile duct cancer) and with Blueprint Medicines to develop Oncomine Dx for new markers of NSCLC. In addition, the company has publicly announced CDx partnerships with GlaxoSmithKline, Novartis and Pfizer. And the Oncomine family of tests are also expanding beyond CDx to IO. Earlier this year, Thermo Fisher launched the RUO-only Oncomine Immune Response Research Assay IO for clinical research trials.

Private Payer Reimbursement?

Another question is the impact of the final NCD on private payer reimbursement for FDA-approved NGS IVDs. Describing the situation at it stands now, Dr. Schilsky told ***IBO***, "The current environment is in flux and so this question is difficult to answer. However, ASCO was supportive of this NCD in general because it represented a first step toward securing consistent nationwide reimbursement for medically appropriate NGS testing."

Both Illumina and Thermo Fisher also view the NCS as progress in this regard. "For non-Medicare plans, commercial payers often follow the lead of CMS in making coverage decisions—in particular for FDA-approved products—and we hope to see that happen with the implementation of this NCD," stated Dr. Hampton. "While private payers make their coverage decisions independently, we do expect that the recognition provided by CMS to FDA-approved NGS tests will impact their decisions on Oncomine Dx coverage favorably," explained Dr. Goswami. Thermo Fisher has announced coverage for the FDA-approved Oncomine Dx by a number of large private insurance providers, including Aetna and UnitedHealthcare.

Although public and private reimbursement is just one issue affecting NGS IVD test usage, it cannot be taken for granted. Asked about the future developments required to grow the use of FDA-approved NGS CDx tests, Dr. Schilsky commented, "That is a complex question. The issue is less about 'growing the use' of these tests and more about defining their appropriate use and clinical utility in the care of patients with cancer." However, reimbursement is an important consideration. "Consistent reimbursement along the lines of this NCD is certainly necessary, as well as a well-defined regulatory pathway to market."

But with NGS being a new diagnostic technology, the NCD's effect in this regard is especially unclear. "Historically, private payers tend to follow CMS' lead more often than not, but this field is simply too new to say anything with

certainty," stated Dr. Schilsky. "ASCO would hope that private payers will provide coverage for well-validated tests that have demonstrable positive impact on patient outcomes."

Along these lines, the NCD has other ramifications. Unlike the earlier draft, the final NCD does not necessitate Coverage with Evidence Development, which requires additional collection of clinical data to determine effectiveness, for non-FDA-approved test or tests without an FDA-approved CDx for the specific type of cancer. "ASCO would also stress the need for ongoing evidence development to improve the reliability of these tests," stated Dr. Schilsky. "The elimination of Coverage with Evidence Development as a means of speeding insight into a critical/complex component of treatment overlooks an important opportunity to accelerate and improve insight into their application and demonstration of their utility."

The Future?

Helped by both FDA approvals and public and private payer reimbursement policies, It is clearly just the beginning for the use of NGS IVD tests. Both Illumina and Thermo Fisher Scientific are moving forward to expand the market with new testing modalities. With NGS CDx tests now FDA and CMS approved, and progressing for CDx IO testing, NGS liquid biopsy testing is set to follow. "Liquid biopsy is likely to become the next frontier as evidence emerges demonstrating the relative performance of genomic testing from tissue and plasma," explained Dr. Hampton. As Dr. Goswami told ***IBO***, "These developments should lead to the rapid extension of NGS-based FDA approved tests to liquid biopsy and immuno-oncology-based tests that help doctors better analysis approaches to better understand and address cancer."

South Korea Slightly Increases Science R&D Budgets

On March 13, the Korea Institute of Science and Technology Evaluation and Planning (KISTEP), a government-affiliated research institute operating under the Ministry of Science, ICT and Future Planning, released the English edition of its biannual report on R&D survey and analysis, entitled "Main Science and Technology Indicators 2017–2." The international comparison data in the publication is largely based on the Organization of Economic Co-operation and Development's global R&D survey and statistics analysis up to December 2017.

The South Korean government announced earlier this month that it increased R&D funding 1.1% in the 2018 budget, with over $6 billion of the total budget, or 34%, allocated to the Ministry of Science, ICT and Future Planning (see ***IBO*** 3/15/18). This slight growth is part of a continuing trend of incremental increases in South Korean R&D funding, which is reflected in the latest KISTEP report through growing funding for biotechnology imports and exports, as well as small bumps in basic, applied and development research.

Gross Domestic Expenditure on R&D (GERD)

South Korea has been amongst the top 10 countries for R&D expenditure for almost a decade. In 2016, KRW 69.4 trillion ($65.4 billion at KRW 1,067.58 = $1), or 4.24% of the country's GDP, went towards R&D, ranking South Korea in fifth place for global GERD. Although South Korea's GERD is less than countries such as China, France, Germany, Japan and the US, it is the highest among them as a percentage of GDP. Since 2012, South Korea's GERD as a percentage of GDP has stayed above 4.0%; in contrast, GERD as a percentage of GDP for China, France, Germany, Japan and the US have been in the 1.7%–3.40% range over the same time period.

Percentage of GERD by Type of R&D in Major Countries

	South Korea (2016)	China (2015)	France (2014)	Japan (2015)	UK (2014)	USA (2015)
Basic Research	16.0	5.1	24.4	11.9	16.9	17.2
Applied Research	22.5	10.8	37.6	19.9	43.3	19.4
Development Research	61.5	84.2	34.7	63.7	39.8	63.4

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The government and public research institutions ranked highest in GERD in 2016 by performance sector in South Korea, representing 78% of total GERD. This figure is akin to China, Japan and the US, but is higher than France, Germany and the UK.

However, universities in South Korea represented only 9% of GERD by performance sectors in 2016, which is lower than France, Germany, Japan, the UK and the US, yet is 2% higher than China. Business enterprises represent 13% of GERD in South Korea, similar to the aforementioned countries.

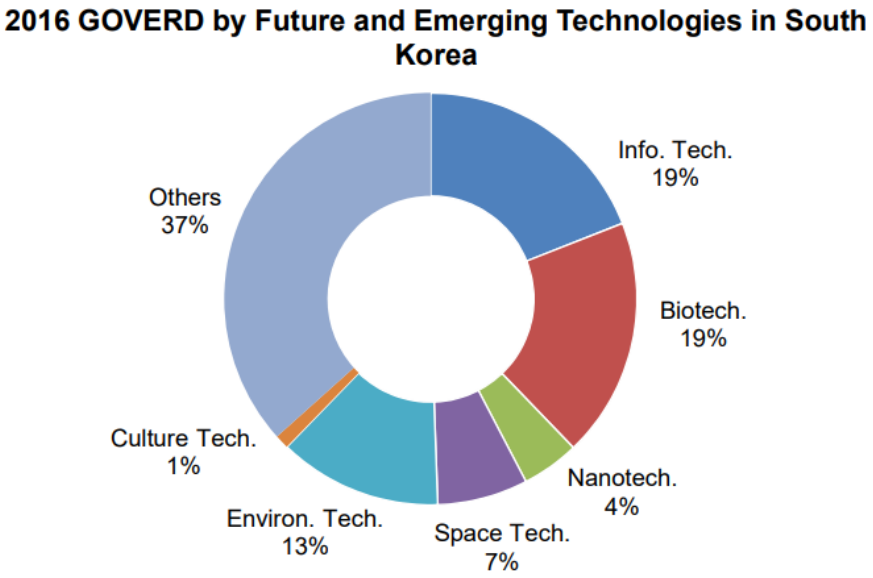
By source of funds, GERD in South Korea was largely propelled by the private sector in 2016, which contributed KRW 52.3 trillion ($49.0 billion), or three-quarters of total GERD. The government spent KRW 16.4 trillion ($15.4 billion), or 24% of total GERD, while the remaining 1%—KRW 649.6 billion ($612 million)—came from international sources. Approximately 62% GERD was allocated to development research, with applied and basic research representing 23% and 16%, respectively.

Future and emerging technologies have been a major focus for South Korean R&D for the past six years. As with previous years, information technology represented the greatest GERD at 33%, or KRW 23.5 trillion ($22.0 billion) in 2016. This was followed by nanotechnology, which made up 12% at KRW 8.5 trillion ($8.0 billion), and environment technology, which represented 9% at KRW 6.3 trillion ($5.9 billion). Biotechnology made up 8% at KRW 5.6 trillion ($5.3 billion). Biotechnology, environment technology and nanotechnology GERD all slightly decreased in 2016, with biotechnology and nanotechnology dropping one percentage point each, and environment technology falling four basis points.

Regionally, Gyeonggi continued to have the greatest GERD, as has been the case since at least 2011. In 2016, GERD in Gyeonggi was KRW 33.1 trillion ($31.0 billion), up 3.8%, representing 48% of total GERD in South Korea. Seoul followed, with a 2016 GERD of KRW 10.4 trillion ($9.8 billion), up 4.5%. Seoul made up 15% of total GERD, while Daejeon represented 11% with GERD of KRW 7.3 trillion ($6.8 billion), a 9.3% jump.

Business Enterprise and Government Intramural Expenditure on R&D (BERD and GOVERD)

Business enterprises received 4.2% of total BERD from the government in 2016, down one percentage point. The vast majority of BERD, or KRW 48.0 trillion ($45.0 billion), in South Korea was for the manufacturing industry, with KRW 5.5 trillion ($5.2 billion) allocated to coke, refined petroleum products, chemicals and chemical products, and rubber and plastic products. As a percentage relative to sales in South Korea, BERD has been steadily increasing over the past few years, reaching 3.2% in 2016.



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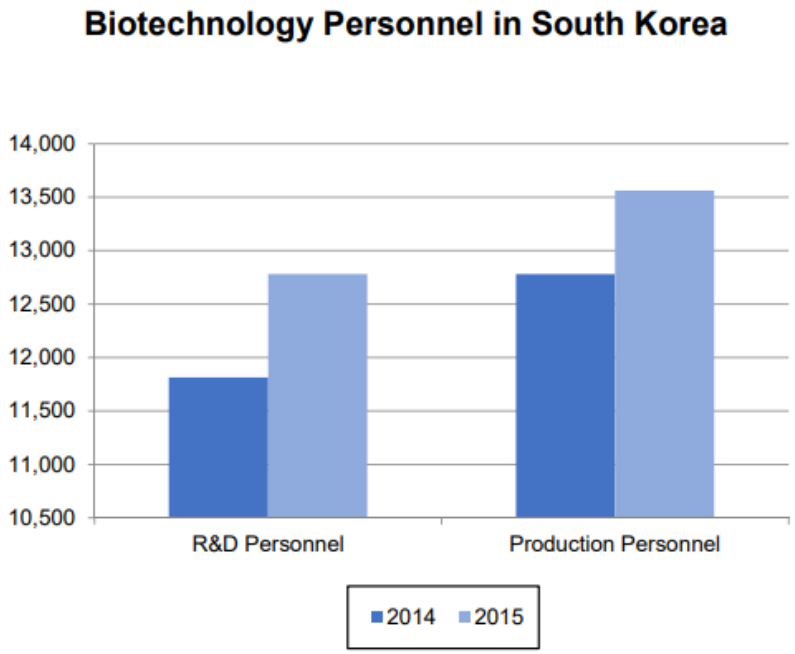
GOVERD in South Korea has also been on a progressive rise since 2013, totaling KRW 19.0 trillion ($17.8 billion) in 2016, up one percentage point. GOVERD by performance sector was unchanged, with research institutes making up almost 50% of total GOVERD at KRW 8.8 trillion ($8.3 billion), just as in 2015. Universities, business enterprises and ministries' GOVERD also increased nominally, again representing 23%, 22% and 3% of total GOVERD at KRW 4.3 trillion ($4.0 billion), KRW 4.2 trillion ($3.9 billion) and KRW 628 billion ($590.4 million), respectively.

GOVERD in federal ministries remained flat as well. The Ministry of Science, ICT and Future Planning received the highest GOVERD in 2016 at KRW 6.5 trillion ($6.1 billion). The Ministry of Agriculture, Food and Rural Affairs' GOVERD of KRW recorded 196.9 billion ($185.1 million), while the Ministry of Health and Welfare received KRW 519.1 billion ($488.0 million). GOVERD at the Ministry of Food and Drug Safety has remained flat since 2014, receiving KRW 81.7 billion ($76.8 million) in 2016.

Biotechnology in South Korea

In 2015, the South Korean government announced plans to focus on the nation's biotechnology industry, with eight government ministries investing a combined KRW 2.38 trillion ($2.17 billion) into the sector and 86% of those funds allocated to R&D (see ***IBO*** 8/31/16). In March 2016, a committee to simplify and expedite the policymaking process in the biotech industry was established by the government, and later in the year, a biotech fund of KRW 80 billion ($74.9 million) was created for startup companies in the industry.



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Although 2016 data is not yet available, the KISTEP report reflects these initiatives, with trends and personnel in the industry incrementally increasing over the past few years. In 2015, the country had a biotech output of KRW 8.4 trillion ($7.9 billion), up 10.7%. Biotech exports also increased in 2015, jumping 26.5% to KRW 4.3 trillion ($4.0 billion). Domestic demand and biotech imports remained flat in 2015 at KRW 5.6 trillion ($5.3 billion) and KRW 1.4 trillion ($1.3 billion), respectively.

Pittcon 2018 New Products: Part 2

IBO has compiled a summary of new products (introduced within the last six months) at Pittcon 2018. Part 1 of the survey appeared in the March 15 issue (see ***IBO*** 3/15/18). The list is not intended to be comprehensive.

Atomic Spectroscopy

Malvern PANalytical showed its Claisse Le Doser-12 sample preparation system, which weighs and dispenses flux for up to 12 samples for fusion preparations, providing time savings over the existing single-sample Le Doser. The Claisse Le Doser-12 is priced at about $35,000.

Introduced in November 2017, with the first shipments made before the end of the year, the 1080 TOC Analyzer from **OI Analytical** (**Xylem**) provides a low-cost combustion-only system for the measurement of total organic carbon. The system features a longer catalyst life and can test water samples with a dynamic range from 50 ppb to 2,000 ppm. The system is priced under $30,000.

Thermo Fisher Scientific unveiled a new application-specific version of its iCAP TQ triple quadrupole ICP-MS. The iCAP TQs is designed to handle applications from the semiconductor industry, such as detecting trace impurities in semiconductor-grade water and other ultrapure materials. The system can be run with both hot and cold plasma, and as either a single quadrupole or triple quadrupole with the collision cell, allowing great flexibility in applications. The first shipments are expected in about a month.

GC

Alpha MOS introduced a new addition to the Heracles product line with its Heracles NEO. The new system improves the sensitivity of electronic nose based on a flash GC and FID detector system. QC for the food and beverage industry is the main application. The first shipment will be this month with a price range of $90,000–$120,000.

APIX Analytics introduced the Chrompix 2, a miniaturized GC system with 4 modular inlets that allow the running of 4 different samples simultaneously with 4 different carrier gases. A typical application for this system is the high-throughput analysis of natural and industrial gases. The system will be ready for shipment in May.

Thermo Fisher introduced the TSQ 9000 Triple Quadrupole GC-MS/MS for routine high-throughput laboratory applications. It is designed to replace the TSQ 8000, intended to dramatically improve ease of use and is particularly suitable for food labs.

Thermo Fisher also presented the ISQ 7000 Single Quadrupole GC-MS system, designed for analysis in food, environmental and forensic labs. Both instruments utilize a vacuum probe interlock that can be inserted into the front of the instrument to extract the ExtractaBrite ion source, thus allowing routine maintenance without the need to vent the MS.

General Analytical Techniques

AMS Alliance showcased three new products: the iCinac Wireless, Smartchem 450 and Futura 3. The iCinac Wireless provides continuous real-time pH, temperature and redox measurements for the dairy industry. The system is useful for monitoring the acidification of lactic ferments in milk. Futura 3 is a new Continuous Flow Analyzer (CFA) that can run multiple parameters simultaneously on 16 parallel channels. This system is dedicated to the analysis of parameters for the environmental, water and beverage industries. The Smartchem 450 is a fully automated direct analyzer capable of running 450 tests per hour. This system is ready for shipment with a price range of $50,000–$60,000.

SE International introduced the Radiation Alert Monitor 1000, a handheld portable radiation monitoring device that can detect alpha, beta, gamma and X-rays with high sensitivity. The device is equipped with a Bluetooth connection, and is suitable for both lab settings and in-field industrial applications. The product is ready for shipment with a price range of $500–$700.

Informatics and Software

Eppendorf showcased VisioNize, its software solution to support laboratory workflow that will be launched during the summer. The system can remotely detect and monitor all instruments connected to the same internet network. Customized notifications of instruments' status, errors, users schedules and calibrations are received in the user's email account. VisioNize can be used on a computer or in its iOS App, allowing the user to check devices in real time.

LabVantage presented its packaged LIMS solutions, configured to specific industries such as pharmaceuticals, biobanking, food and beverage, oil and gas, and diagnostics to ensure a faster, lower-cost and modern technology cloud hosted for users. The prefigured solutions will enable quicker implementation times, which can result in lower costs. The platform comes in different languages, which is particularly well-suited for companies with branches around the world. The already-validated system ensures that it can be used within highly regulated industries straight away.

Realworld One, a spinoff of **IKA**, introduced its new virtual reality product that is to be launched at the ACHEMA trade fair in June. The company develops customized software for the chemical, pharmaceutical, cosmetic and food industries priced at €2,900/month ($3,570/month). The system allows users to interact with other people in their company remotely. It can be used for training sales representatives, interacting with customers, holding meetings

with international teams and more. The 3D models include real live shapes and photorealistic texture of components and mechanical parts, and full interactivity.

Lab Automation

Scinomix showcased its new automated capper that will officially launch in the fourth quarter in the US. It can cap up to 48 vials in 6 minutes and uncap them in 4 minutes, and is particularly well-suited for working with cryovials. The system can be used standalone or integrated with a robotic arm.

Sirius Automation introduced its MiniTasker for everyday lab tasks such as analytical weighing, sample ID, sorting, dilutions, standard preparation and aliquoting. With times of 3 sec/sample for sorting and 6 sec/sample for weighing, this small footprint system can host up to 20 microplate racks. The system costs between $37,000 and $70,000 depending on the configuration.

Teledyne Cetac launched its SimPrep automated system for preparing samples, diluting standards and dispensing. It features a wide range of syringes from 20 µL to 50 mL to serve multiple applications. It is designed to serve environmental, mining, pharmaceutical and soil labs.

Lab Equipment

Gyrozen introduced its benchtop multi-purpose centrifuge 1696R last month. With a total capacity of 1000 mL, the system has a speed of up to 16,000 rpm. It can be used with a swing rotor that can bring the speed to 3,700 rpm. It is currently being sold in Europe for $15,000 and is projected to start selling in the US soon.

Orto Alresa launched in January its Dilitcen 22, a benchtop centrifuge with a capacity of 4 x 1,000 mL and a max speed of 14,300 rpm. It features an unbalance location system that stops the run if there is an unbalance and informs the users where the unbalance is occurring. The system also includes a touchscreen interface and is priced at €7,000 ($8,630).

Rephile showcased its Genia water system that will launch in June worldwide. A single water system can accomodate a large number of dispensers with wireless communication, so dispensers can be placed freely around the lab. A glove friendly touchscreen provides users total monitoring capabilities and control over water quality, operation parameters, the status of the system, dispensers, etc. The software can hold up to two years of data storage. The system design provides customer maximized versatility.

Scientific Industries introduced its US-manufactured Genie Temp-Shaker 100 and 300 orbital shaking incubators. The 100 model has a speed range of 20–100 rpm, and the 300 model's speed goes from 35 rpm to 300 rpm. Both feature temperature control and a three-way access clear dome temperature chamber for easy sample access. These instruments not only retain the temperature throughout the unit due to a unique airflow technology, but are also lightweight with a small footprint to fit in any lab. The list price is $27,000 for the 100 model and $3,150 for the 300 model.

LC

Pharmafludics showcased its micro-chips technology with µPAC technology and trap columns. The trap columns remove possible contaminants, while the µPAC provides a higher peak capacity compared to a regular packed column. The new trap columns will be available for shipment in the next two months.

Shimadzu Scientific Instruments launched its new i-Series Plus Integrated HPLC that offers an automated sample pretreatment function. The new system seeks to improve throughput with around 140 samples analyzed overnight and an easy-to-use interface, which has become a current trend in many chromatography systems. The I-Series Plus Integrated HPLC is ready for shipment with a price range of $40,000–$50,000.

Sykam introduced its Amino Acids Analyzer S435, an improved version of the previous automatic Amino Acids Analyzer S433 model. Typical applications for this system are in the food, pharmaceutical and clinical sectors. The product will be ready for shipment in April.

Sykam also introduced the Ion Chromatography S153-A system, which enables simultaneous analysis of anion and cation with the same sample injection. This modular system is mainly applicable in water and waste water analysis. The product is ready for shipment.

In December 2017, **Teledyne Tekmar** launched the Atomx XYZ VOC system for purge and trap. The system incorporates an xy autosampling system derived from the **Teledyne Cetac** business. It offers dilutions, methanol rinsing and a unique methanol extraction technology. The system is priced in the mid-$30,000s.

Thermo Fisher launched an improved version of the highest end of its Dionex HPIC product line with the Dionex ICS-6000 HPIC. The new system is equipped with Unity Remote Service Software, which enables remote monitoring to reduce system downtime and early detection of errors and issues. It also has the Thermo Fisher Consumables Device Monitor which embeds memory tags into each IC consumable and notifies users when they need to change them.

Materials Characterization

Malvern Panalytical introduced Morphologi 4, a system improvement with 25% faster measurements and sharper image compared to its predecessors, according to the company. The new system is fully automated with Morphologically Directed Raman Spectroscopy technology that is able to characterize particles ranging from less than one micron to a millimeter in size. Morphologi 4's applications include R&D and QC for the pharmaceutical sector, and also forensic analysis.

NETZSCH introduced the DSC 204 F1 phoenix, a versatile DSC for a wide variety of applications. It is equipped with two different sensor types to provide higher sensitivity and an automatic sample changer to enable higher throughput. DSC is mainly used in QC and method development in the polymers industry. The system is ready for shipment with a price tag of around $70,000.

Molecular Spectroscopy

PAC introduced the OptiFuel, an FT-IR analyzer for measuring the physical and chemical properties of gasoline, diesel and jet fuel. It uses an Attenuated Total Reflection (ATR) single flow cell in conjunction with FT-IR to analyze petroleum samples. The unit boasts an enormous library of finished fuels, to which the customer can add. It is expected to begin shipping in April for a price ranging from about $30,000 to the low $50,000s, depending on the configuration.

Shimadzu Scientific Instruments showcased its IRSpirit FTIR Spectrophotometer, a small and lightweight analyzer for performing quick identification and quantitative sample analysis. Designed for all kinds of users, including those in pharmaceutical and teaching labs, the instrument is moisture resistant, boasts a strong signal-to-noise ratio comparable to that of larger units and features a very wide sample compartment. Released in February, it currently sells from about $18,000 to $20,000.

Singapore-based **Tip Biosystems** introduced the Photopette personal handheld photometer for on-the-spot analysis of liquid samples. Designed in the shape of an automatic pipette, the device can hold up to six wavelengths and is useful for applications such as cell density, Bradford protein assays, cell-viability assays, turbidity and more. Priced at $2,900, it was released in September 2017 in Southeast Asia, but its market reach is expected to expand to other regions, including China and Australia.

Vitl Life Science Solutions introduced the Lu-mini benchtop luminometer, optimized for the measurement of biological and chemical luminescence reactions. Accepting round or square cuvettes with which to measure samples, the instrument features a touchscreen interface, programmable testing parameters, a storage capacity of up to one thousand test results and USB connectivity for data transfer purposes. The instrument is planned to be

launched officially at Analytica in April and will sell for $21,000.

Sample Preparation

The week before the show, **Anton Paar** began shipping its Multiwave 7000 microwave digestion system. The most novel aspect of the new system is the pressurized digestion cavity, allowing for different materials to be digested simultaneously, rather than in batches of similar samples. The system can achieve a maximum temperature of 300 °C and pressures up to 199 bar. The system is priced at about $70,000.

Ohaus launched in March its HT lysing bead mill homogenizer. The system's flexibility enables the use of multiple sample and tube configurations. High-speed linear motion helps quickly process samples. The homogenizer costs approximately $8,800, and is targeted primarily at government and academic labs. Color-coded tubes come with beads to process different sample types.

SPEX SamplePrep showcased its 2010 Geno/Grinder cell lyser and homogenizer for sample preparation. The system provides better insulation than older models and safety-latch protection. With a capacity of 96 x 6 titer plates, the system can also hold tubes from 2 mL to 50 mL that can be processed at room temperature with a speed between 500 rpm and 1,750 rpm. The programmable touchscreen control panel can save up to 500 protocols. The system can be purchased from $60,000.

Surface Science

HORIBA introduced a new model in its line of x-ray microscopes, the XGT-9000, featuring improved resolution and other advances. The system provides both XRF analysis/imaging and transmission x-ray imaging of samples. Full vacuum, partial vacuum and atmospheric modes are supported. The system is expected to begin shipping in the second quarter at a price comparable to the previous system, the XGT-7200.

JEOL debuted its JSM-IT200 SEM, expected to begin shipping soon. This is another entry in JEOL's InTouchScope line of SEMs. Priced starting at $125,000, the compact microscope has a motorized stage and a larger EDS detector than the IT100.

JEOL also discussed a new version of its ARM200F with the addition of a dual Wien-filter monochromator, providing Electron Energy Loss Spectroscopy (EELS) with extremely high-energy resolution—as low as 14 meV. The Monochromated ARM200F allows atomic-scale imaging, as well as the ability to probe interesting energetic phenomena, such as phonons and surface plasmon resonance, with high-resolution EELS spectra.

For many years, **Velab** has manufactured microscopes under private label arrangements. At the end of last year, the company transformed itself, offering products to customers under its own name. The company offers several product lines of microscopes for education, industry and research, with prices ranging up to about $5,000.

Fujifilm to Acquire Cell Culture-Supplier for $800 Million

Tokyo, Japan 3/19/18; Santa Ana, CA 3/29/18—Fujifilm has agreed to purchase Irvine Scientific Sales and IS JAPAN from JXTG Nippon Oil & Energy for $800 million in stock. Irvine Scientific and IS JAPAN provide cell culture media and products to the biopharmaceutical, cell therapy and medical markets. Fujifilm commented in its press release, "With the acquisition of ISUS and ISJ, Fujifilm will now be able to provide a broad product portfolio from biopharmaceuticals to in vitro fertilization and cell therapy, strengthening its global business." Fujifilm stated that it expects to benefit from the acquired companies' synergies with its biopharmaceutical contract development and manufacturing business, research and production in the area of regenerative medicine, and its reagent business.

Later this year, Fujifilm plans to open a new site in Boston, Massachusetts, to support research and manufacturing of new drugs. The site will also support its FUJIFILM Diosynth Biotechnologies, Cellular Dynamics International (CDI) and Wako Pure Chemical businesses, as well as the newly acquired businesses. These businesses will also maintain their existing US sites. Effective April 1, CDI will be renamed Fujifilm Cellular Dynamics and Wako Pure Chemical will become Fujifilm Wako Pure Chemical.

Irvine Scientific and IS JAPAN together have 350 employees, according to a spokesperson for Irvine Scientific. Key Irvine Scientific product lines, according to her, include BalanCD chemically defined media for bioproduction, the PRIME-XV product portfolio for stem cell culture and immunotherapy, and a range of products for assisted reproductive therapy, including the Vit Kit and Continuous Single Culture brands. "The company is also considered a leading expert on media development, optimization and manufacturing services," she told **IBO**.

Fujifilm entered the cell culture–media reagent market last year with its purchase of reagent supplier Wako Pure Chemical (see **IBO** *12/31/16). That purchase along with Fujifilm's acquisitions of CDI (see* **IBO** *3/31/15), which provided the firm expertise in iPSC preparation, and of J-TEC, which added technology for somatic stem cell culturing, has strengthened the company's capabilities in cells, cell culture media and cytokines, and scaffolds, according to Fujifilm, in order to build its Regenerative Medicine business. The latest purchase bolsters distribution, R&D and QC for cell culture media, according to Fujifilm. Regenerative Medicine, Pharmaceuticals and Bio CDMO, Medical Science and Life Science units make up Fujifilm's Healthcare business.*

Oxford Nanopore Raises Over $100 Million

Oxford, UK 3/20/18—Oxford Nanopore Technologies, developer of portable, real-time, long-read, low-cost sequencers, has raised $140 million. New investors included GIC, China Construction Bank International and Hostplus. The new funding will be used to expand the company's manufacturing capabilities and support R&D, including investments in further development of the PromethION for high-throughput modular sequencing and the Flongle for small, single-test sequencing. "Our business is moving quickly, from personal sequencers into high-end sequencing and distributed analyses," commented Oxford Nanopore Dr. Gordon Sanghera. Bryan Yeo, chief Investment Officer of Public Equities at GIC, stated, "Oxford Nanopore has a unique business model of providing accessible, realtime DNA analysis technologies that can be applied to pocket-sized or industrial installations. We believe this will continue to drive growth in their user base as well as in new applications for DNA or RNA sequencing." Oxford Nanopore also plans to establish a 34,000 ft^2 (3,159 m^2) purpose-built facility in the UK.

In total, Oxford Nanopore has raised £1.5 billion ($2.1 billion at £0.71 = $1), according to the Financial Times. Dr. Sanghera told the newspaper that he expects order value to more than double to total $75 million this year.

The company currently offers four nanopore-based sequencing systems (the portable MinION and Flongle and the desktop GridION and PromethION), and is developing the SmidgION smartphone sequencer, as well as sample preparation kits and the VolTRAX sample preparation device. Excluding the MinION, the reagent cost for each device is $99 per run and feature price per flow cell range from $500–$2,200 according to the company's website. The company recently reported that the PromethION, designed to compete with existing industrial-scale systems and featuring 48 flow cells, each running as many as 3,000 channels, has demonstrated runs of 150 Gb per data cell.

Thermo Fisher Scientific Purchases Human ID Firm

Carlsbad, CA 3/16/18—Thermo Fisher Scientific has acquired IntegenX for an undisclosed amount. IntegenX's RapidHIT platform provides DNA analysis for forensic and law enforcement applications. "The development of rapid DNA technology provides law enforcement with the ability to generate results while a suspect is still in custody," commented Rosy Lee, vice president of Human Identification for Thermo Fisher. "Such a dramatic reduction in time from sample to result has led to an increased demand from law enforcement agencies and aligns with our strategy to expand our leadership position in the human identification market." Thermo Fisher stated that the platform complements its human identification chemistries, qPCR and capillary electrophoresis technologies.

IntegenX technology combines PCR and capillary electrophoresis to provide a portable solution for forensic DNA testing. Thermo Fisher has worked with the company to supply PCR reagents for the system (see **IBO** *9/15/17). Thermo Fisher will be able to expand the systems' distribution channels through its existing law enforcement sales channels, where it sells molecular spectroscopy and life science products. According to FBI, This Week, the Agency plans expand the use of the technology to booking stations in major cities next year.*

SEM Maker Adds 3D X-ray Imaging

Brno, Czech Republic 3/27/18—TESCAN ORSAY, which supplies electron, ion and light microscopy systems, has purchased Belgian-based XRE. XRE develops and manufactures dynamic 3D and 4D x-ray imaging systems, including micro-CT x-ray systems, for geoscience, materials and life science applications. "X-ray tomography provides unique contextual information for many of the existing imaging modalities we serve to date, and our customers are increasingly using the approach of multi-modal imaging within their characterization workflows to enable new science," commented TESCAN ORSAY CEO Jaroslav Klima.

Asked about the market and product development advantages that TESCAN ORSAY has as a manufacturer of both technologies, Maroš Karabinoš, director of Marketing & Sales for the company, told **IBO**, *"TESCAN ORSAY HOLDING can offer fast global market reach for the new product line. Generous R&D spending within the group is another advantage. Synergies between SEM and micro-CT systems are becoming more obvious at the customers' end and TESCAN ORSAY HODLING will continue to support them."*

Mr. Karabinoš told **IBO** *that XRE's micro-CT technologies are differentiated from other such systems through their throughput and use of dynamic tomography. "Through a combination of hardware optimizations and software developments, XRE systems are uniquely designed for fast acquisitions (capable of tomographies in < 10 sec) that facilitate new dynamic tomography experiments in the laboratory." As he explained, "This enables new research, such as in situ studies or time dependent ('4D') investigations where you may monitor the structural change in a sample over time (e.g,. fluid flow, mechanical compression, temperature, etc.). These 'dynamic' studies have historically only been possible at large synchrotron radiation facilities, and are now increasingly possible in your own laboratory."*

Describing differentiation, Mr. Karabinoš also emphasized the uniqueness of XRE's CoreTOM , a multi-scale micro-CT system optimized for 3D imaging and dynamic 4D imaging of rock core samples, and the DynaTOM, calling it "the only gantry-based (stationary-sample) micro-CT system available on the market [which] is designed for maximum flexibility for dynamic tomography, continuous rotation and in situ tomography." Other differentiators listed by him are applications focus, collaboration and support, and system modularity.

Unchained Labs Diversifies Its Biopharmaceutical Downstream Offerings

Pleasanton, CA 3/27/18—Unchained Labs, which provides solutions for biologics researchers, has purchased Rap.ID for an undisclosed amount. Rap.ID provides systems for particle identification during biopharmaceutical development and QC. The company's Single Particle Explorer identifies particles by their shape and their chemical and elemental fingerprints. Its Layer Explorer measures the thickness and consistency of silicon oil, which is used to dispense drugs from injectable devices. The company also provides contract services. "These products are great additions to our biologics tools arsenal. We can now help our customers identify the source of any particle that shows up in their process," stated Unchained Labs Founder and CEO Tim Harkness. "This acquisition expands our portfolio firmly downstream into biologic quality control." Unchained Labs generates annual revenues of more than $50 million.

Unchained Lab's sixth acquisition, the transaction was funded in part by a $17 million Series D financing. The Single Particle Explorer systems combines sample preparation, microscopy, image microscopy, and Raman and LIBS analysis. The purchase further adds to Unchained Lab's focus on analytical instruments for biopharmaceutical

QA/QC.

SYGNIS to Add Multi-surface Immunoassay Technology

Heidelberg, Germany and Cambridge, UK 3/19/18; Heidelberg, Germany and Cambridge, UK 3/20/17—Publicly held SYGNIS has announced its intention to acquire Australia-based TGR Biosciences, a protein-capture technology company, for €6.5 million ($8.0 million at €0.81 = $1) in cash, in addition to post-completion and earnings payouts. TGR Biosciences' trailing 12-month sales are expected to total €3.6 million ($4.4 million) at the time of closing, with a three-year CAGR of 23% and EBITDA of approximately 40%. "We are very excited about this acquisition, as this will add immediately to our top and bottom line," said Sygnis CEO and CSO Dr. Heikki Lanckriet. "We are not only strengthening our technology portfolio and our customer base, but this will significantly increase our business scale and our visibility in the market." TGR Biosciences' will be sold under Sygnis' Expedeon brand.

To fund the purchase, Sygnis raised €4.2 million ($5.2 million) through a private placement of shares, including 3 million new shares at a price of €1.40 ($1.73) per share. The company plans a €2 million ($2.5 million) debt financing to complete the deal.

With the purchase, Sygnis will add TGR Biosciences' CaptSure single-plex and multiplex immunoassay technology, which can be used with ELISAs, beads and lateral flow systems. According to TGR Biosciences' website, it has licensed its technology to three companies. Past press releases announce partnerships with Abcam and PerkinElmer.

Agilent Seeks Access to Divested Varian Technology

Washington, DC 3/30/18—Agilent Technologies has submitted an application to the US Federal Trade Commission (FTC), requesting approval for a cross-license agreement that would allow the company use of ICP-MS intellectual property that it lost access to as part of gaining FTC approval to buy Varian (see ***IBO*** 7/31/09).

Agilent sold Varian's ICP-MS business to Bruker in 2010 (see ***IBO*** 3/15/10). Although Agilent retained certain ICP-MS intellectual property, it was required to grant a irrevocable, royalty-free license to Bruker and not use technology for ICP-MS, only for ICP-OES. Bruker sold the product line to Analytik Jena acquired the product line in 2014 (see ***IBO*** 8/15/14).

Agilent proposes in the request to license its ICP-OES technology to Analytik Jena in exchange for a license to the ICP-MS technology with no financial commitment. The cross-license would be non-exclusive and non-sublicensable.

The specific patents listed in the request are Agilent US Patent No. 7,852,471 ("Power Generator for Spectrometry"), which covers the so-called Hosemans solid-state RF (SSRF) generator, an alternative to vacuum tube systems. As described in Agilent's request, SSRF generators are smaller, do not require routine maintenance and have a lower cost of goods.

Agilent argues in the request that the cross-license would benefit both companies and not threaten competition. The public comment period for the proposal is opened for 30 days.

The unique arrangement would allow each company to develop new products for ICP-OES and ICP-MS, both markets they currently participate in. Other companies offering both technologies are Hitachi High-Technologies, PerkinElmer, Shimadzu, SPECTRO Analytical Instruments (AMETEK) and Thermo Fisher Scientific.

Final 2017 Figures for IBO Sales Indexes

Since the publication of the February 28 issue of ***IBO*** (see ***IBO*** 2/28/18), which included estimated figures for the

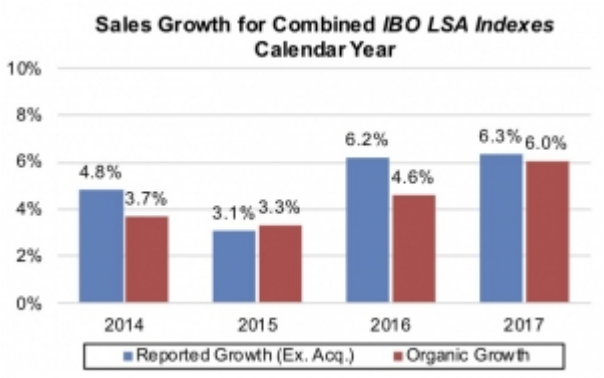
***IBO** Life Science and Analytical Instrument Indexes* (*LSA Indexes*), quarterly and annual estimates have been finalized for three companies: Bio-Rad Laboratories Life Science, Merck KGaA Life Science and NanoString Technologies. The updated financial results affect the ***IBO** Life Science Index* (*LS Index*) as well as the *LSA Indexes*.

Life Science and Analytical Instrument Indexes

Combined calendar year fourth quarter 2017 sales for the 22 companies or business units in the *LSA Indexes* grew 8.6% organically, versus 4.3% in the prior fourth quarter. Sequentially, organic sales growth was up 2.4 percentage points.

Against the nine-month organic growth rate, fourth quarter 2017 organic sales growth was up 3.5 percentage points. For calendar year 2017, *LSA Indexes* revenue grew 6.0% organically, compared to the prior year's organic growth of 4.6%.

In 2017, the *Indexes*' adjusting operating margin reached 21.0%, an increase of 100 basis points.



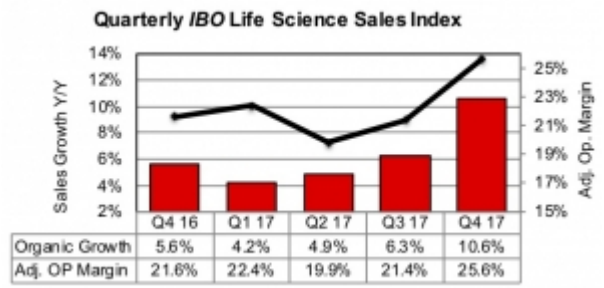
Click to enlarge

Life Science Index

***IBO**'s Life Science Index* sales advanced 10.6% organically for the fourth quarter 2017. Sales growth was up 4.3 percentage points sequentially and 5.0 percentage points versus the prior year period.

Adjusted operating margin for the *Index* increased 3.9 percentage points to 25.3%. Sequentially, adjusted operating margin rose 4.2 percentage points.

Full-year 2017 sales growth for the *Index* rose 6.5%, compared to 5.3% in 2016. Adjusted operating margin for the same period also showed an increase, totaling 25.6% versus 21.6% in the prior period.



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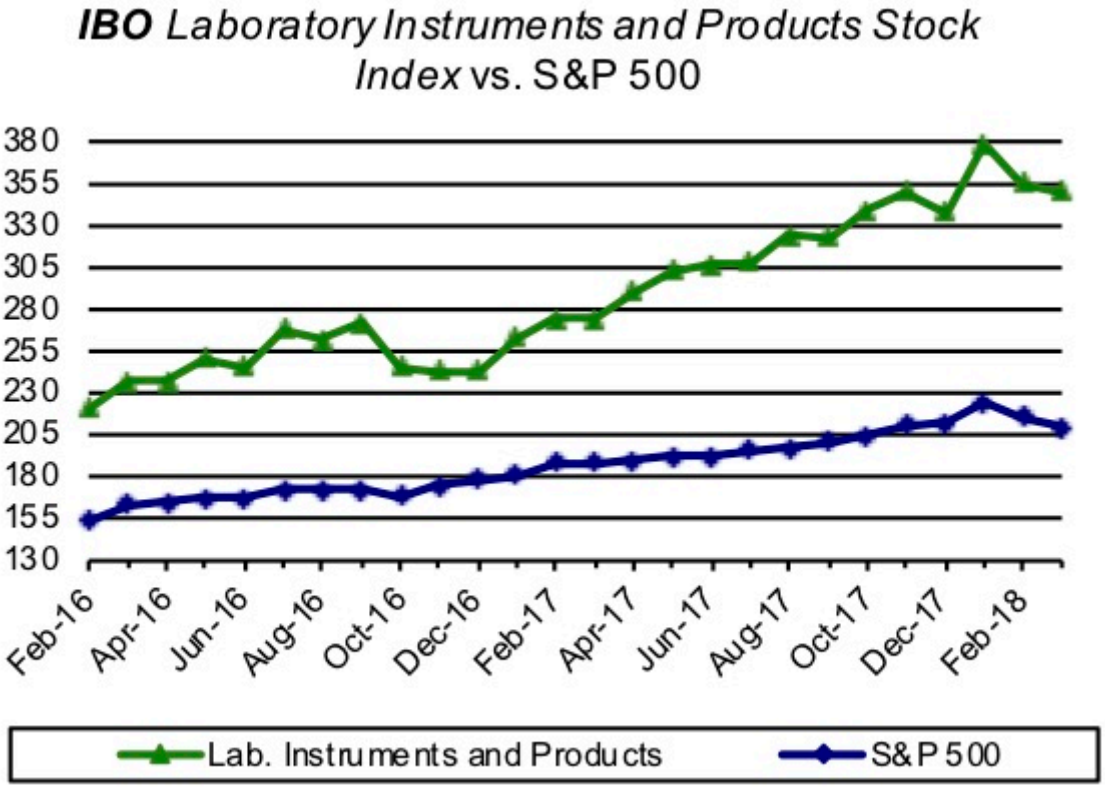
IBO Stock Indexes Continue Their Slide

In the midst of looming uncertainty due to President Trump's tariff announcements during the month, which focused specifically on steel and aluminum, US equity markets moved downwards as investors remained cautious. The good news was a revision to GDP estimates. The US GDP for the fourth quarter of 2017 increased at a rate of 2.9%, the third estimate from the Bureau of Economic Analysis, representing a 40 basis point increase over the second estimate. The growth in the GDP rate was primarily driven by strong personal consumption expenditures, private inventory investment and local government spending.

US markets slipped for the month, with the Dow Jones Industrial Average down 3.7% to 24,103.11. The S&P 500, along with the NASDAQ Composite, fell 2.7% and 2.9%, respectively. The S&P 500 finished the month at 2,640.87, while the NASDAQ Composite dropped to 7,063.44. The three indexes peaked for the month on March 12, after which all three then began their downturns.



Laboratory Instruments and Products Stock Index

Companies in ***IBO***'s Laboratory Instruments and Products mostly fell as the *Index* slid 1.5% to 350.19. Year to date, however, the *Index* is up 3.8%. Strong movers in the *Index* included **Kewaunee Scientific** and **NanoString Technologies**. Both delivered double-digit share growth for the month.

On March 1, **Kewaunee Scientific** announced a dividend payout of $0.17, or a 2.28% payout ratio, payable on March 23. The company's share price advanced 14.5% to $34.05 for the month, up 17.4% year to date. **NanoString Technologies** closed the month at $7.51, a 17.2% increase. On March 8, Morgan Stanley gave the stock a $12.00 price target.

Bio-Techne shares also grew for the month, up 6.9% to $151.04. Year to date, Bio-Techne shares are up double digits, increasing 16.6%. On March 1, Deutsche Bank gave the stock a "buy" rating, along with a price target increase from $154.00 to $163.00.

Conversely, **Enzo Biochem**, **Fluidigm** and **Pacific Biosciences** share prices fell double digits this month. Enzo Biochem shares fell 13.4% to $5.48, while Fluidigm shares decreased 13.7% to $5.84. On March 2, Fluidigm announced an exchange of convertible senior notes, worth a total of $125.0 million. Pacific Biosciences' share price

sunk 13.9% to $2.05. Year to date, Pacific Biosciences shares are down 22.3%.

On March 5, BMO Capital Markets presented a “market perform” rating for **Becton, Dickinson** shares, along with a $249.00 price target. Despite the rating, Becton, Dickinson’s share price fell 2.4% for the month, finishing at $216.70.

Bio-Rad Laboratories received an upgraded price target of $290.00 from Wells Fargo on March 20, representing a $10.00, or 3.6% increase. The investment group also gave the stock an “outperform” rating. But, for the month, Bio-Rad Laboratories shares fell 7.4% to $250.08.

Mettler-Toledo share price decreased 6.7% for the month, closing at $575.03. On March 1, Deutsche Bank reiterated its “hold” rating for the stock, but increased the price target from $600.00 to $630.00

Company	Date Rep.	Fiscal Quarter	2018 Adj. EPS	Analyst Consensus	Vs. Estimate	YOY Growth	2017 Adj. EPS
Laboratory Instruments and Products Stock Index							
ENZ	12-Mar	Q2	($0.04)	---	---	100.0%	($0.02)
HBIO	1-Mar	Q4	$0.05	$0.05	$0.00	25.0%	$0.04
NSTG	7-Mar	Q4	($0.34)	($0.43)	$0.09	-38.2%	($0.55)

Diversified Laboratory Stock Index

The *Index* fell 2.2% for the month, closing at 264.67. **Xylem** shares grew the fastest, up 3.1% to $76.92. On March 6, Cowen Group gave the stock a “buy” rating, along with an $80.00 price target. Conversely, **Honeywell** shares fell 4.4% to $144.51, the most in the *Index*.

Corning shares decreased 4.1% for the month, closing at $27.88. Year to date, Corning shares have fallen 12.8%. On March 9, Citigroup lowered its price target for the stock from $35.00 to $32.00.

Shares of **Danaher** rose 0.1% to $97.91 in March, benefiting from a price target increase of $108.00 by Credit Suisse. Additionally, on March 23, Danaher entered into a credit agreement with Bank of America, for a total amount of $1.0 billion.

Roper Technologies’ share price also advanced, increasing 2.0% to close at $280.69. On March 6, Cowen Group gave the stock a “buy” rating, along with a price target of $310.00. On March 12, Roper Technologies announced a dividend payout of $0.41, representing a 0.58% payout ratio, payable on April 23.

International Stocks

In Asian Pacific countries, most of the indexes that ***IBO*** follows slumped, falling low- to mid-single digits. Indonesia’s Jakarta Composite, along with the Philippines’ PSEi, both fell 6.1%. The former finished the month at 6,202.84, while the latter ended at 7,950.86. Conversely, South Korea’s Kospi advanced 1.2%, the highest of the Asia Pacific indexes ***IBO*** tracks, finishing at 2,455.67. Taiwan’s TAIEX and Malaysia’s KLCI both grew moderately, up 0.8% and 0.3%, respectively.

Asia Pacific shares in the ***IBO*** Stock Table delivered improved results as **JEOL** advanced 10.5% to ¥979.0 ($9.26 at ¥106 = $1). Similarly, **Precision System Science** and **Shimadzu** also experienced significant growth, up 9.8% and 9.9%, respectively. Precision System Science closed the month at ¥658.0 ($6.22), while Shimadzu finished at ¥2,992.0 ($28.30). However, **GL Sciences**, **Hitachi High-Technologies** and **Techcomp** were all down for the month, down 5.5%, 1.7% and 4.9%, respectively. GL Sciences closed at ¥1,668.0 ($15.78), down 22.2% year to date. Conversely, Techcomp finished at HKD 2.33 ($0.30 at HKD 7.8 = $1), up 30.2% year to date.

In the European region, the indexes that ***IBO*** follows ended mostly in negative territory for the month, with Sweden's OMX Stockholm 30 down 3.0% to 1,535.35, the largest drop within the region. France's CAC Index similarly fell 2.9%, closing at 5,167.30. Italy's FTSE MIB fell the least, down 1.0% to 22,411.15.

European shares in the ***IBO*** Stock Table grew moderately for the month as overall growth was in the low to mid-single digits. **Scientific Digital Imaging** shares grew the most, advancing 7.4% to £0.33 ($0.46 at £0.71 = $1), up 33.0% year to date. Conversely, **Horizon Discovery**'s share price fell the most, dropping 18.7% to £1.50 ($2.11). Year to date, share price fell 37.5% for the company.

Also decreasing significantly is **Biotage**, down 9.6% for the month to finish at SEK 71.40 ($8.50 at SEK 8.4 = $1). **Sartorius** shares remained flat for the month, closing at €102.50 ($126.12 at €0.81 = $1), but is up 35.9% year to date. **Merck KGaA** announced its earnings on March 8, along with the news to increase dividends. The company increased its dividend payout by €0.05 ($0.06), amounting to a total of €1.25 ($1.54) per share. However, Merck KGaA shares fell 1.5% for the month, closing at €77.84 ($95.78).

Company: Exchange	Market Value (US M)	52 Week Range Low ($)	High ($)	Price 3/31/18	Change 1 Month	Change YTD	P/E (ttm)	EPS (ttm)
Laboratory Instruments and Products								
Agilent Technologies: n	$20,865	48.01	75.00	$66.75	-2.7%	-0.3%	32	2.10
Becton, Dickinson and Company: n	$42,691	174.13	248.39	$216.70	-2.4%	1.2%	47	4.60
Bio-Rad Laboratories: n	$6,647	184.97	273.87	$250.08	-7.4%	4.8%	317	0.79
Bio-Techne: o	$4,533	95.68	151.89	$151.04	6.9%	16.6%	77	1.95
Bruker: o	$4,775	21.83	36.53	$29.92	-2.4%	-12.8%	32	0.94
Enzo Biochem: n	$485	6.27	12.04	$5.48	-13.4%	-32.8%	NM	-0.05
Fluidigm: o	$147	2.52	7.05	$5.84	-13.7%	-0.8%	NM	-2.22
Harvard Bioscience: o	$130	2.25	5.20	$5.00	6.4%	51.5%	NM	-0.09
Illumina: o	$29,282	156.50	248.97	$236.42	3.7%	8.2%	45	5.25
Kewaunee Scientific: o	$81	20.95	34.74	$34.05	14.5%	17.4%	21	1.60
Luminex: o	$874	17.68	22.42	$21.07	7.4%	7.0%	32	0.66
Mettler-Toledo: n	$16,651	420.03	697.26	$575.03	-6.7%	-7.2%	35	16.45
MTS Systems: o	$1,021	44.65	58.70	$51.65	5.5%	-3.8%	41	1.27
NanoString Technologies: o	$349	7.03	20.70	$7.51	17.2%	0.5%	NM	-2.05
Pacific Biosciences: o	$488	2.02	5.74	$2.05	-13.9%	-22.3%	NM	-0.90
PerkinElmer: n	$7,602	50.59	84.49	$75.72	-0.8%	3.6%	21	3.60
QIAGEN: o	$7,399	30.20	35.00	$32.31	-4.1%	4.5%	101	0.32
Thermo Fisher Scientific: n	$74,564	146.08	220.10	$206.46	-1.0%	8.7%	35	5.88
Waters: n	$14,496	140.93	220.20	$198.65	-2.9%	2.8%	29	6.78
Diversified Laboratory								
AMETEK: n	$15,253	50.44	78.16	$75.97	0.3%	4.8%	32	2.38
Corning: o	$27,996	25.97	35.10	$27.88	-4.1%	-12.8%	12	2.31
Danaher: n	$60,528	78.97	104.82	$97.91	0.1%	5.5%	29	3.38
Honeywell	$108,185	117.13	165.13	$144.51	-4.4%	-5.8%	22	6.60
Illinois Tool Works: n	$51,642	125.96	179.07	$156.66	-3.0%	-6.1%	24	6.52
Roper Technologies: n	$25,097	189.58	284.57	$280.69	2.0%	8.4%	41	6.89
Teledyne Technologies: n	$5,747	119.74	201.40	$187.17	0.7%	3.3%	32	5.88
Xylem: n	$11,317	46.67	79.83	$76.92	3.1%	12.8%	45	1.72
Laboratory Instruments and Products				**350.19**	**-1.5%**	**3.8%**	**62**	
Diversified Laboratory				**264.67**	**-2.2%**	**-2.7%**	**30**	
Dow Jones Industrial Average				24,103.11	-3.7%	-2.5%		
S&P 500				2,640.87	-2.7%	-1.2%		
NASDAQ Composite				7,063.44	-2.9%	2.3%		
Region Company	Market Value (Local M)	52 Week Range Low (L)	High (L)	Price 3/31/18	Change 1 Month	Change YTD	P/E (ttm)	EPS (ttm)
Pacific Shares								
GL Sciences: t	¥17,076	900	2,345	¥1,668	-5.5%	-22.2%	12	¥144.19
Hitachi High-Technologies: t	¥540,625	3,710	5,680	¥5,060	-1.7%	6.5%	21	¥245.97
HORIBA: t	¥286,671	5,750	8,290	¥8,240	4.7%	21.4%	22	¥375.69
JEOL: t	¥50,714	488	1,006	¥979	10.5%	53.2%	136	¥7.21
Precision System Science: os	¥13,077	346	1,011	¥658	9.8%	-0.5%	NA	-¥71.44
Shimadzu: t	¥598,358	1,722	3,145	¥2,992	9.9%	16.8%	34	¥87.56
Techcomp: hk	HKD 521	1	3	HKD 2.33	-4.9%	30.2%	30	¥0.01
European Shares (London)								
Abcam: l	£2,168	7.99	12.90	£12.39	1.6%	17.4%	60	£0.21
Halma: l	£4,144	9.13	13.41	£11.79	-0.5%	-6.4%	34	£0.34
Horizon Discovery: l	£231	1.47	2.95	£1.50	-18.7%	-37.5%	NA	-£0.12
Oxford Instruments: l	£601	7.00	11.74	£7.41	0.4%	-12.9%	NA	-£0.44
Scientific Digital Imaging: l	£22	0.19	0.34	£0.33	7.4%	33.0%	28	£0.01
Spectris: l	£2,757	22.25	28.69	£26.94	0.5%	8.3%	101	£0.27
European Shares (Other)								
Biotage: st	SEK 3,818	38.80	94.60	SEK 71.40	-9.6%	-15.0%	39	SEK 1.83
Datacolor: s	CHF 124	640.50	899.50	CHF 850.00	0.6%	1.2%	21	CHF 41.39
Merck KGaA: g	€ 11,946	87.23	115.20	€ 77.84	-1.5%	-13.3%	21	€ 3.68
Sartorius: g	€ 6,028	65.20	108.00	€ 102.50	0.0%	35.9%	60	€ 1.70
Tecan: s	CHF 2,159	148.80	217.80	CHF 202.20	4.4%	-0.2%	42	CHF 4.84

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.

Total Nitrogen Combustion Analyzers

For water analysis, two common elements of interest to measure are carbon and nitrogen. Both are found in all living things and provide a measure of the level of biological matter in the water sample. Consequently, water quality measurements typically limit the maximum allowable amount in drinking water, wastewater, runoff, etc.

Carbon is more associated with the total contamination level in the water, and measurements of Total Organic Carbon (TOC) are very common in water testing in various applications. Nitrogen's effects are somewhat more complex. Since proteins are based on nitrogen-bearing amino acids, nitrogen analysis provides a measure of protein content. However, simpler nitrogen compounds, typically based on ammonia, act as fertilizers, and their presence in water can have direct effects on the ecosystem.

For many applications, both elements are of interest, so it is most convenient to measure them simultaneously. Although there are a number of specific techniques for TOC, it turns out that the combustion method can also be used for nitrogen. Consequently, instruments for TOC typically offer the option of a separate module for the detection of the Total Nitrogen (TN) in the sample, also commonly called the Total bound Nitrogen (TN_b).

In combustion analysis, the sample is introduced into a furnace, which typically operates at temperatures of 1200°C or higher. The sample is generally combusted in the presence of a catalyst, which ensures the complete oxidation of the sample. For TOC analysis, the resultant carbon dioxide is detected via non-dispersive IR spectroscopy. For nitrogen, which is converted into nitric oxide, a few different methods can be applied; among them are chemiluminescence, electrochemistry and IR spectroscopy.

Applications are primarily related to water testing in a variety of settings. Water utilities are a major source of demand for nitrogen analysis, as regulations set limits for drinking water as well as for treated wastewater. More generally, environmental testing has many uses for nitrogen testing of surface water and seawater, as well as for monitoring industrial releases. The industrial processes themselves may also require certain limits on contamination in waters used in the process.

The connection with nitrogen as a fertilizer also makes this analysis important for the agriculture and food industries, in order to monitor runoff from agricultural land. Beyond simple water testing, soil can also be analyzed, and this also has importance in both agricultural and environmental testing.

A number of the major TOC vendors also supply TN analysis. While some vendors offer integrated TOC/TN systems, it is more common that the nitrogen module is sold as a separate optional component. On its own, the TN module is priced at about $10,000, but a complete TOC/TN system can run from about $25,000–$50,000.

A few vendors also offer dedicated nitrogen-only combustion analyzers. Shimadzu leads the market, as it does the general TOC market. The next most prominent vendors are Analytik Jena (Endress + Hauser) and OI Analytical (Xylem). Other significant market participants include Elementar, Skalar and Teledyne Tekmar (Teledyne Technologies).

Total Nitrogen at a Glance

Leading Vendors:

- Shimadzu
- Analytik Jena (Endress + Hauser)
- OI Analytical (Xylem)

Largest Markets:

- Utilities
- Environmental
- Agriculture

TN Module Cost:

- $7,000–$15,000

Pharmaceuticals

Experts in academia, cancer research and the pharmaceutical industry have been voicing concerns over the spike of clinical trials for cancer immunotherapies, believing that many of the trials will not be completed due to a lack of participants. The increase in trials has resulted in duplicate trials being conducted, which are using up resources that could go to novel drugs.

Many combination studies with checkpoint inhibitor drugs have also been on the rise. Checkpoint inhibitors prevent a cancer to conceal itself from the patient's T cells by blocking cell-surface proteins. Since 2011, 6 checkpoint inhibitors have been approved by the FDA for cancers including melanoma and lung cancer; however, approximately only 20% of patients respond to the drugs. Despite this, the hype over the health and commercial potentials of checkpoint inhibitor drugs has skyrocketed their growth in clinical trials. At a minimum, 1105 combination studies are currently testing drugs using these approved checkpoint inhibitors, according to the Cancer Research Institute (CRI).

The FDA lacks the authority to provide oversight to immunotherapy trials so long as they are passing the Administrator's standards. Because of this, cancer research institutions such as the CRI, as well as experts in the industry, are calling for improved coordination in the execution of clinical trials involving checkpoint inhibitors, such as eliminating single site trials in exchange for multicenter clinical trial designs.

Source: *Science*

Electronics

The first consumer products incorporating metamaterials, which can make objects appear invisible, are now being brought to market. Metamaterials are specially engineered materials that "hide" objects by bending light rays away from them. The breakout product using metamaterials could be satellite antennas for internet users. Metamaterials make the antennas weigh less and thus easier, and potentially, cheaper to use in cars and other modes of transport. Kymeta, which is developing the systems, has raised over $200 million from investors, including Bill Gates. Echodyne is developing metamaterials for use in radars. Both companies are spin outs of Intellectual Ventures, which continues to form more companies. Separately, the firm Metamaterials Technologies is working on using them to block lasers.

Source: *Financial Times*

Clinical

Under the new Centers for Medicare and Medicaid Services' (CMS) fee schedule, clinical labs will face cuts of up to 30%. According to industry experts, only labs with diverse portfolios, healthy bottom lines and efficient operations will survive the cut, putting smaller labs at a disadvantage. The labs that receive most of their lab testing payments from CMS tend to be nursing homes, but with the new cuts, the fate of those labs is up in the air and many may eventually be forced out of business. For example, Aculabs, which conducts testing for over 320 nursing and assisted living facilities in 4 states, will record an estimated 30% cut in total revenues over the next 3 years, according to the company's CEO. Other labs that may be negatively affected include rural hospitals, small health clinics and physician office labs.

The labs that will benefit from the cuts will be ones that have proprietary testing services. As an example, payment for the Oncotype DX Breast Cancer test by Genomic Health will increase 12% to $3,873. Advanced Diagnostic Laboratory Tests (ADLT), which is a new category of assays defined by the CMS as "tests developed and offered by a single lab that use a unique algorithm to analyze multiple DNA, RNA, or protein markers," may also receive positive pricing, at least initially. After the initial period, payment for a new ADLT will depend on the weighted median private payer rate, like the other tests on the CMS fee schedule.

Many labs, especially smaller ones, are unable to determine data on testing volumes and contract revenues due to their inadequate financial systems. This is because these systems are mostly implemented by LIMS vendors or lab technicians as opposed to financial experts. With these new cuts in place, industry experts state that it would behoove labs to prepare and review contract pricing models to ensure they are receiving the proper payments.

The diagnostics sector is expected continue to undergo many transformations, with experts predicting that the changes will lead to greater industry consolidation and the shutting down of many labs. This change in landscape may also propel labs to collaborate with other labs to create networks, such as the Joint Venture Hospital Laboratories Network, which negotiates contracts for 120 hospital labs across 3 states.

Source: *American Association for Clinical Chemistry*

EU

According to recent data from the European Commission, Horizon 2020 funding success rates in Central and Eastern Europe EU-member countries is steadily catching up to nations in the Western region of the continent. Issues regarding grant funding and infrastructure still linger, however, making the catch up still difficult.

The EU average of success rates for winning grants in 2016 was 14.8%. Countries such as Romania, Poland and Hungary had success rates between 12% and 16%. The Czech Republic received funding for 19% of its projects, while Italy and Spain received funding for 17% and 14% of their projects, respectively. However, overall, over 60% of applications come from a select group of countries: France, Germany, Italy, Spain and the UK, leaving the success rates for funding in Eastern and Central European countries off balance. A major cause for this is the fact that Eastern and Central European countries, which were deeply affected by the 2008–2009 European economic crisis, have been mainly focused on reducing national debts and balancing their countries' budgets. Because of this, governments in these countries are not able to prioritize increasing R&D budgets, although they are optimistic they will reach their target budgets within the next decade.

One way countries can get an extra boost for science innovation is through Horizon 2020's successor initiative, the Framework Program (FP9), which can help fund better infrastructures for research and, ideally, help attract foreign researchers as well.

Source: *Science|Business*

Russia

While Russia has a long road ahead when it comes to recovering its once thriving national science and research system, President Vladimir Putin has pledged to make science and innovation among the country's top priorities. Russia has a rich history in regards to scientific contributions, but with the collapse of the Soviet Union, many of the country's regional institutions and infrastructures fell apart as well.

Over the last decade, Putin's administration has incrementally increased the country's science budget, with annual R&D spending now approximately 1% of the nation's GDP. In 2018, the Russian government designated RUB 170 billion ($3 billion), a 25% increase, for fundamental R&D. According to the NSF, between 2006 and 2016, Russia's scientific publishing output increased by over 50%, placing the country amongst the top 10 countries in terms of published research articles and ahead of countries such as Australia, Canada and Switzerland. However, state-

funded science and discovery-to-commercialization efforts still fall short in Russia, and excessive bureaucracy and state control over researchers' work have also pushed many Russian scientists to leave the country.

Source: *Nature*

China

The Chinese government has announced the restructuring of the primary science funding agency in the country, changing the method by which scientists receive R&D funding for the first time in over 30 years. The National Natural Science Foundation, primarily dedicated to promoting research and innovation as well as managing science funding, was originally under the cabinet, and ran as an independent central government agency. Control of operations and management of the Foundation was carried out by scientists and researchers. Last year, the Foundation supported over 120,000 scientific research teams in the nation, investing CNY 30 billion ($4.75 billion). Now, the Foundation will be under the Ministry of Science and Technology, which has a slightly larger budget and spent CNY 37 billion ($5.85 billion) on R&D for advanced technology, such as high-power batteries for electric cars.

The main issue with the change lies in the ultimate difference of ideologies between the two government bodies. The Foundation promotes exploratory research and encourages scientists to study solutions to problems that interest them the most; in contrast, the Ministry promotes R&D for practical and applicable projects, with scientists required to clearly indicate the usage of their research and submit detailed schedules with deadlines for when the project will be completed. By moving the Foundation under the Ministry, some Chinese researchers believe the development of fundamental research may become compromised.

Proponents for the reshuffling posit that the change in management will optimize the information flow between fundamental research and field application. The restructuring may help researchers get more funding for projects sooner, with a chance of finding relevant commercial applications quicker as well.

Source: *South China Morning Post*

Broad-based Companies

Company Announcements

In February, **QIAGEN** announced the opening of QIAGEN Business Services Manila, a shared services facility in the Philippines. The center will provide services related to supply chain management, customer care and accounting, as well as technical services and other sales support activities for the US and APAC. Headcount is expected to reach 200. QIAGEN's existing Shared Service Center is based in Wroclaw, Poland, and has more than 350 employees.

Agilent Technologies announced in February a strategic scientific collaboration agreement with **Imperial College London**. Agilent will support Imperial with a broad range of instruments to equip a new Agilent-sponsored Measurement Suite. Application areas that will benefit include clinical diagnostics, biopharmaceuticals, energy and chemicals, environmental science, food testing and agriculture, materials research and proteomics.

Thermo Fisher Scientific announced in March that it plans to build a $35 million, 86,111 ft^2 (8,000 m^2) pharma services supply chain facility in Rheinfelden (Baden), Germany. The facility will increase European capacity for cold and ambient clinical trial materials. Construction is scheduled to begin in the fourth quarter and take 12–18 months. As many as 200 employees will work at the site.

KentOnline reported in March that **Thermo Fisher Scientific** is proposing to relocate a manufacturing facility for plastics from Ashford, UK, to existing facilities in Mexico, China and Denmark by 2019, potentially affecting 170 positions.

Harvard Bioscience's 2017 revenues declined 2.6% to $101.9 million (see Bottom Line), with organic revenues

down 0.2%. Direct sales accounted for 65% of revenues, while self-manufactured products represented 62%. Adjusted operating profit rose 89.2% to $3.7 million. For 2018, sales are forecast to reach $118–$123 million, up 16%–21%.

In March, **PerkinElmer** signed a letter of intent with India's **Biotechnology Industry Research Assistance Council** to work together under a five-year partnership to promote India-led startups and innovators in the areas of biomedical, biotechnology and public health. According to BIRAC, the partnership covers medical devices, point of care, algorithms and information technology/software in areas such as maternal health, newborn health and food.

Hitachi HighTechnologies will open the 6,997 ft^2 (650 m^2) Hitachi HighTech Science Park Shanghai Lab in China in June to promote the development, sale and support of analytical instruments. Hitachi HighTech will also utilize the Shanghai Lab as a total solution service center for XRF and thermal analysis instruments. The lab will brings the company's global lab structure to 9 locations in 5 countries.

Judges Scientific's 2017 revenues grew 24.6% to £71.4 million ($91.5 million) (see Bottom Line), including organic growth of 17.7%. Adjusted operating profit rose 52.3% to £10.9 million ($14.0 million), driven by strong revenue growth and currency effects. By segment, Materials Sciences revenue increased 21.0% to £34.1 million ($43.7 million), while Vacuum sales grew 28.2% to £37.3 million ($47.8 million).

FOSS' 2017 revenues increased 4.9% to DKK 2,226 million ($337 million) (see Bottom Line), including organic growth of 6.9%. Sales of process instruments grew 35% to make up 8% of revenues. Products launched within the last three years made up 23% of sales. The company also highlighted its new Digital Services for monitoring and remote control of FOSS instruments from a virtual control room. Over the next five years, the company plans to invest over DKK 1 billion ($152 million) in R&D.

Orders and Sales of Note

In March, **Northern Illinois University** (NIU) announced the launch of a five-year equipment-purchase program involving its Division of Research and Innovation Partnerships and **Shimadzu**. NIU will receive discounted rates on the equipment, a suite of software, and technical support and maintenance through the Shimadzu Partnership for Academics, Research and Quality of Life initiative. A laboratory housing most of the new instruments will also be established. Instrumentation provided will include an XRF spectrometer, as well as triple quadrupole LC/MS, MALDI-TOF and GC/MS systems.

GC & GC/MS

Company Announcements

In January, **VIC Technology Venture Development** announced the formation of **Zebra Analytix** (see ***IBO*** 3/15/18) to develop and commercialize miniaturized GC systems based on MEMS technology exclusively licensed from **Virginia Tech University**.

VUV Analytics announced in January that its revenue more than tripled in the fuels and petrochemicals segments in 2017. Accomplishments include the company's first super-major upstream customer and its first top-five inspection and certification customers. Internationally, sales have been made in the Middle East and the company received its first order in Saudi Arabia.

Orange Photonics announced in March that **Eden Labs** will be offering its LightLab cannabis analyzer, a GC-spectroscopy system, for measuring cannabinoid content.

INFICON's fourth quarter 2017 Security & Energy sales grew 12% to $10.5 million. Full-year Security & Energy revenue declined 23% to make up 7% of total sales. The company's quarterly financial presentation described the outlook for 2018 for the segment as challenging.

Software and Informatics

Company Announcements

In February, **Certara**, a decision-support technology and consulting organization for drug development, announced the purchase of Germany-based **BaseCase Management**, a data visualization SaaS company for health economic evidence. BaseCase joined Certara's Strategic Consulting Services division.

Schrödinger, a provider of advanced molecular simulations and enterprise software solutions and services, launched in February the Schrödinger Cryo-EM Initiative (SCI) to develop breakthrough medicines leveraging cryo–electron microscopy technology and its drug discovery platform. The SCI utilizes a network of Cryo-EM centers.

ELN firm **KineMatik** named **EOH** as an authorized provider for South Africa in February.

In February, **Strand Life Sciences** received an investment from **Quadria Capital**.

LIMS company **Autoscribe Informatics** opened an office in Adelaide, South Australia, in February, and formed a subsidiary.

Genedata announced in February the completion of a collaboration with **Boehringer Ingelheim** to develop a new request management system to efficiently manage each step in the biotherapeutic protein production and QC process within R&D and simultaneously monitor all R&D operations.

In February, LIMS provider **Accelerated Technology Laboratories** (**ATL**) announced the integration of **SciCloud**'s ELN with its LIMS, offering a single document management solution for analytical QC, R&D studies and manufacture batch records.

Accelerated Technology Laboratories (**ATL**) named Steve Chase as CEO in March.

BioDiscovery partnered with **Thermo Fisher Scientific** in March to create an assay plus analysis cancer research package consisting of its Nexus Express for OncoScan software for Thermo Fisher's Cancer Research portfolio. BioDiscovery initially began the OEM partnership three years ago with **Affymetrix** (now Thermo Fisher). The new tailored software solution offers copy number detection and downstream analysis for the OncoScan CNV Assay.

In March, **Certara** launched its Quantitative Systems Pharmacology (QSP) Immuno-oncology Simulator Consortium. QSP combines computational modeling and experimental methods to examine the mechanistic relationships between a drug, the biological system and the disease process. The consortium brings together leading biopharmaceutical companies in a pre-competitive environment to develop cooperatively a QSP Immuno-oncology Simulator that can model clinical populations of cancer patients. This is the company's second QSP consortium.

Product Introductions

In February, **Enamine**, a chemical research organization and producer of building blocks and screening compound libraries, and medicinal chemistry software firm **BioSolveIT** launched the REAL Space Navigator for access to more than 640 million pharma-oriented molecules in a virtual chemical space.

In March, **Enamine** and **ChemAxon** launched an online resource to allow researchers worldwide to explore the chemical space of Enamine's REAL database for use in virtual screening.

Certara released in February version 10 of the D360 data informatics platform for discovery scientists. It offers new visualization features, including the ability to chart chemical structures for direct structural activity display and new data-presentation capabilities.

CDD (Collaborative Drug Discovery) announced in February that its CDD Vault platform for drug discovery

informatics is now also an ELN, enabling the collection of unstructured and structured data.

In February, **Genedata** introduced the Genedata Profiler 11.0 for automated biomarker identification for optimizing clinical trial patient selection. New features include the Clinical Subject Data Management Module, designed to integrate and process phenotypic and omic data gathered from patients in clinical drug trials.

In March, **Sapio Sciences** debuted the Exemplar LIMS/ELN system, which includes features to enable high levels of data representations, analysis and visualizations. The company also introduced Exemplar ELN Essentials, an SaaS solution with credit card–based, monthly billing.

elementar launched in March the ArDB software platform for the creation, management and utilization of databases of analytical results and data visualizations. Features include the ability to generate 2D and 3D plots, and perform multivariate analysis.

Sales and Orders of Note

In February, **Genedata** announced that **Pfizer** licensed its Genedata Bioprocess enterprise platform for integration with its existing Genedata Biologics platform.

In March, ELN firm **LabArchives**, a research data management platform with 235,000 users, announced its users have surpassed 100 million user activities.

Sequencing

Company Announcements

Edico Genome announced in February a partnership with the **Murdoch Children's Research Institute's Victorian Clinical Genetics Services,** which will deply its DRAGEN Bio-IT Platform, marking the platform's first deployment in Australia.

Edico Genome entered into a partnership in February with **InterSystems**. Edico Genome's DRAGEN Clinical Genomics Information System will leverage InterSystems' HealthShare HealthConnect to exchange and communicate genetic information in a bidirectional manner, streamlining clinical NGS workflows.

Edico Genome introduced in March the DRAGEN Global Distribution Partner Network to provide new and existing DRAGEN customers with regionally focused technical and sales support, thus streamlining the purchase and implementation of DRAGEN.

In March, **Nightingale Health**, which provides NMR-based biomarker analysis assay for early disease detection, partnered with **PerkinElmer**. Nightingale's comprehensive metabolic profiling of blood biomarkers complements PerkinElmer's global genomic lab testing platform of newborn screening, diagnostic testing and genetic sequencing services.

WuXi NextCode announced in March a genomics partnership with **Google Cloud**. The partnership includes hosting WuXi NextCODE's core suite of capabilities on Google Cloud and its availability on the Google Cloud Launcher marketplace. In addition, key Google genomics and research tools will be integrated and deployable in tandem with the WuXi NextCODE platform, beginning with the DeepVariant secondary analysis pipeline, alongside other open-source analysis pipelines and tools available through Google Cloud Platform.

WuXi NextCode named Rob Brainin, executive vice president and COO, as CEO in March.

In March, **QIAGEN** partnered with **Natera**, a developer of NGS assays that include non-invasive prenatal genetic testing and the analysis of circulating tumor DNA, to develop cell-free DNA assays for use on QIAGEN's GeneReader NGS System. Under the 10-year agreement, QIAGEN will pay Natera $40 million in upfront licensing fees and prepaid royalties in the first quarter. Natera is also eligible for an additional $10 million of milestone payments, as

well as ongoing royalty payments.

Pierian Dx announced in March a partnership with **Cancer Genetics**, a firm which enables precision medicine in oncology from bench to bedside through the use of oncology biomarkers and molecular testing. The companies will provide a comprehensive precision oncology testing and workflow solution to enhance patient care by combining their respective Clinical Genomics WorkSpace and Focus::NGS offerings.

In March, **Charité–Universitätsmedizin Berlin** joined **Thermo Fisher Scientific**'s Companion Dx Center of Excellence Program.

Illumina announced in March a partnership with the **Chinese Medical Genetics Association of the Chinese Medical Doctor Association** to launch whole-genome sequencing for Chinese children with birth defects and rare undiagnosed diseases. This is a global extension of Illumina's iHope program, set up in the US in 2017, to help children who do not have insurance or family financial means to do genomic testing.

In March, **Biocept**, a commercial provider of liquid biopsy tests, entered into a non-binding memorandum of understanding with **Thermo Fisher Scientific**. The companies will work together to validate Thermo Fisher's Oncomine liquid biopsy panels and Biocept will become a Thermo Fisher "Center of Excellence" for oncology-focused liquid biopsy initiatives.

Product Introductions

In March, **BC Platforms** debuted the GeneVision end-to-end solutions from raw genome data to patient reports, which uses the **Microsoft Genomics** service. GeneVision utilizes several of BC Platforms' existing pipeline technologies.

Pacific Biosciences introduced in March v 5.1 of its Sequel Software and a new polymerase. With this release, the Sequel System can achieve up to 10 Gb per SMRT Cell for genomic libraries, effectively doubling the throughput when using ultralong inserts (>40 kb) for de novo genome assembly. For targeted and RNA sequencing, customers can achieve up to 20 Gb per SMRT Cell. For long amplicons (>3 kb), the new polymerase increases the number of highquality sequences per SMRT Cell.

In March, **PierianDx** launched Clinial Genomics Services, a full range of expanded services to support adoption of its Clinical Genomics WorkSpace.

Sales and Order of Note

In March, the **University of Texas at Arlington** in partnership with the **University of North Texas Health Science Center**, launched the North Texas Genome Center, which houses five **Illumina** NovaSeq6000 systems.

BC Platforms announced in March that **Gene By Gene**, a provider of integrated multi-disciplinary genetic testing services, has selected its platform to provide a solution for running parallel imputation of genotype data from multiple chips as well as historical data.

In March, **Pacific Biosciences** announced a purchase order for 10 PacBio Sequel Systems from China-based **Annoroad**, a provider of genomic solutions for both clinical testing and life science research.

Thermo Fisher Scientific announced in March that Canada-based nonprofit **Exactis Innovation**, which is involved in the integrated recruiting and matching of cancer patients to clinical studies for targeted therapies, will standardize its Oncomine assays and Ion GeneStudio S5 Series systems. Exactis expects to receive up to two thousand samples annually through its Personalize My Treatment (PMT) program,

Reported Financial Results

$ in Millions USD	Period	Ended	Sales	Chg.	Op. Prof.	Chg.	Net Prof.	Chg.
Enzo Biocem	Q2	31-Dec	$19.5	3.7%	($3.0)	-184.0%	($0.9)	14.4%
Harvard Bioscience	Q4	31-Dec	$27.5	4.0%	$0.7	NM	$1.0	NM
Harvard Bioscience	FYE	31-Dec	$101.9	-2.5%	($0.1)	96.6%	($0.9)	79.9%
HTG Diagnosics	Q4	31-Dec	$7.9	442.2%	($1.7)	67.9%	($1.9)	66.1%
HTG Diagnosics	FYE	31-Dec	$14.8	187.6%	($17.7)	27.2%	($19.0)	27.2%
MTS Systems	Q1	30-Dec	$194.2	-2.6%	$16.5	60.3%	$33.2	1844.3%
MTS Systems (Test)	Q1	30-Dec	$118.2	-9.9%	$5.6	-52.1%	NA	NA
Simulations Plus	Q1	30-Nov	$7.1	30.5%	$2.6	33.0%	$1.7	26.0%
Techcomp	FYE	31-Dec	$199.4	8.9%	$1.5	64.5%	$1.0	60.6%
Techcomp (Distribution)	FYE	31-Dec	$128.9	9.2%	$4.4	-4.0%	NA	NA
Techcomp (Manufacturing)	FYE	31-Dec	$70.4	8.5%	($2.3)	NM	NA	NA
Other Currencies (in Millions)								
Abcam	H1	31-Dec	£112.5	9.8%	£32.7	15.5%	£32.3	63.1%
FOSS	FYE	31-Dec	DKK 2,226.0	4.9%	DKK 564.0	13.7%	DKK 421.0	10.8%
Judges Scientific	FYE	31-Dec	£71.4	24.6%	£10.9	52.3%	£8.9	52.2%
Pfeiffer Vacuum Technology	Q4	31-Dec	€ 156.5	14.3%	€ 10.6	-59.0%	€ 11.7	-34.0%
Pfeiffer Vacuum Technology	FYE	31-Dec	€ 587.0	23.8%	€ 71.4	5.0%	€ 53.8	14.5%

NA = not available, NM = not meaningful