



**Capstone Headwaters**



# **FDA-APPROVED CANNABINOID THERAPIES: NEW OPPORTUNITIES FOR BPOS COMPANIES**

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*Institutional Industry Report*

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## EDITOR'S NOTE

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We welcome you to the third quarterly edition of our Institutional Industry Report on the Bio/Pharma Outsourced Services (BPOS) sector. This installment follows our introductory note (June 2018) initiating coverage of the space and our most recent effort (September 2018), which reviewed the role of BPOS providers in the development of biopharmaceuticals and cell/gene therapies. Today, we address a portion of the industry having special relevance, albeit perhaps for non-obvious reasons, as we focus on the BPOS industry's opportunities to support the development and manufacture of cannabinoid-based drugs. We hasten, however, to dampen any prurient interest in this topic by emphasizing that these drugs have no "mind-altering" effects and will not be available through the marijuana dispensaries popping up like flowers in the spring. They are, rather, what we once called "ethical," i.e., prescription, medications and will be available only from pharmacies upon presentation of a prescription from a licensed caregiver.

Cannabinoid-derived therapies are based on chemical substances peculiar to and extracted from cannabis for their analgesic and anti-inflammatory properties, or on their synthetic analogs; they have no measurable psychoactive effects. First and most importantly, these drugs have an important role to play in pain management compared with existing medications. Of particular and timely interest, two unfortunate properties of many "traditional" pain medications make the rapid evolution of cannabinoid-based pain therapies an important development: (i) the tendency of traditional medications to become progressively less effective over time, prompting patients to increase their dosage, often without professional advice, and (ii) the addictive properties of those that are narcotics, particularly the many that are opiate-based. Consequently, the medical and social services communities are calling

for accelerated development of cannabinoid-based pain therapies to stem the rapidly ascending usage of addictive, and potentially fatal, opioid medications.

We have repeatedly discussed the factors underlying the outsourcing of development and manufacturing services as they relate to pharmaceutical, biopharmaceutical and biotechnology drugs; we have observed a similar evolution in the cannabinoid sector and expect it to accelerate. These drugs will migrate from the outer fringes of acceptability towards mainstream use as they are increasingly perceived as beneficial to patients and as a welcome alternative to traditional narcotic pain medications. Further, as the research community gains a greater understanding of the human endocannabinoid system and its effects on inflammatory and fibrotic disease, the axiomatic importance of cannabinoid and other cannabis-derived therapies will only broaden.

Consequently, BPOS providers of standard CRO, CMO/CDMO and associated services (particularly those that have DEA permits to handle controlled substances!) are likely to become increasingly attractive to the growing number of developers and producers of cannabinoid-based drugs. These drugs are subject to the same FDA development and approval processes as other drugs and biologicals. As such, the volume of contract-based outsourcing work for BPOS providers should accelerate at the same rate for cannabinoids as it has for pharmaceutical and biological medications.

Given the anticipated near-term growth of cannabinoid-based therapies, we expect an accelerating effect on the demand for contract outsourcing of development and manufacturing services by BPOS providers and continued positive trends in the space.

Michael Ewing

## CANNABIS DRUGS: NEW OPPORTUNITIES FOR BPOS COMPANIES

### Breaking New Ground with Epidiolex

The June 2018 FDA approval of Epidiolex, for the treatment of two forms of childhood epilepsy, marks a major milestone in the development of cannabis-based drugs and opens new opportunities for biopharmaceutical outsourcing services (BPOS) companies. In addition to the treatment of epilepsy, cannabis-derived medications have a wide range of potential uses in development including alleviating nausea in chemotherapy patients, treating autoimmune disorders, and managing pain. They may be especially useful as safer and less addictive alternatives to opioids in pain management. We review the most important of these developments below. We note that this report focuses on the potential medical uses of cannabis (marijuana), not on its use as a recreational drug or as an ingredient in foods and beverages.

Although several drugs containing synthetic cannabis ingredients have been approved in recent years, Epidiolex, developed and marketed by GW Pharmaceuticals (GWPH), is the first FDA-approved drug derived directly from the cannabis plant. Epidiolex is an oral solution that contains a purified form of cannabidiol (CBD), one of more than 60 compounds called cannabinoids which are found in cannabis. A number of these cannabinoids are under investigation and development for therapeutic use.

It is important to distinguish CBD from another cannabinoid, tetrahydrocannabinol or THC. Unlike CBD, THC is a psychoactive chemical that can alter brain function and result in changes in perception, mood, consciousness, cognition, and behavior. The U.S. Drug Enforcement Administration (DEA) classifies THC as a Schedule I controlled substance, its most restrictive designation. By contrast, in late September 2018, the DEA reclassified Epidiolex from Schedule I to Schedule V, its least restrictive category, citing its medical use and low potential for abuse.

We believe that this reclassification sets an important precedent for BPOS companies seeking to provide development and manufacturing services for cannabis-based drugs. The reclassification — or “rescheduling” — of new products and product candidates to Schedule V removes restrictions on research, manufacturing, and distribution, lowering risks for outsourcing firms and enabling them to work with medical cannabis companies. It also removes restrictions on physicians prescribing these drugs, thus creating a stronger market opportunity. Looking ahead, we expect medical cannabis companies to turn increasingly to BPOS firms for toxicology and other pre-clinical protocol execution, clinical trial support, manufacturing expertise and capacity, and post-approval marketing and distribution services.

The pathway to approval for Epidiolex is instructive and provides a template for near-term development of other cannabinoid-based therapies that BPOS companies can expect to participate in. Epidiolex has been approved as a treatment for patients with Lennox-Gastaut syndrome and Dravet syndrome, two rare epilepsy disorders. It received an FDA “orphan drug” designation for both

indications and a fast-track designation for Dravet syndrome. Breaking new ground, Epidiolex is the first drug approved to treat Dravet syndrome, a genetic disorder that appears during the first year of life and is associated with severe fever-related seizures. Outside the U.S., Epidiolex is under review by the European Medicines Agency (EMA), with an expected decision date in 1Q19.

In its fiscal 2018 10-K, GW said that it was expanding capacity both in-house and with third-party manufacturers to produce commercial volumes of Epidiolex. It is also expanding its commercial capabilities in Europe as its application for Epidiolex moves forward with EU regulators.

### New Therapies for Difficult-to-Treat Conditions

As noted above, we believe that the approval and subsequent rescheduling of Epidiolex could spur an increase in licensing and M&A activity among companies with assets derived from cannabinoids. These companies, which include Bausch Health (formerly Valeant), AbbVie, and Insys Therapeutics, may receive substantial capital infusions to accelerate development of these assets, providing opportunities for BPOS companies.

Meanwhile, the FDA continues to encourage the development of cannabis-derived therapies. When Epidiolex was approved, FDA Commissioner Scott Gottlieb noted that it served as a reminder that “advancing sound development programs that properly evaluate active ingredients contained in marijuana can lead to important medical therapies. The FDA is committed to this kind of careful scientific research and drug development.” At the same time, he noted that the FDA would take action if it sees “illegal marketing of CBD-containing products with serious, unproven medical claims.”

### Large Potential Market

We believe that the addressable market for medical cannabis is potentially very large. Grand View Research, a market research firm, estimates that the global market for legal medical cannabis products will grow to approximately \$100 billion by 2025.

What is driving this growth? In the U.S., 33 states, along with the District of Columbia and Puerto Rico, have legalized the medical use of cannabis. The therapeutic use of cannabis is also legal in many developed countries, including Australia, Canada, Chile, Czech Republic, France, Germany, Israel, the Netherlands, Poland and Spain.

These legalization efforts have lifted restrictions on research and allowed clinical trials to be conducted on the use of cannabis in pain management (especially as a less addictive alternative to opioids), the treatment of nausea in chemotherapy patients, and as a treatment for cancer, autoimmune disorders (Crohn’s disease, multiple sclerosis), and various forms of epilepsy. There is currently limited safety and efficacy data for most of these treatments, so clinical trials are needed to support approvals.

## CANNABIS DRUGS: NEW OPPORTUNITIES FOR BPOS COMPANIES

### Current Commercialized Drugs... and Pipeline Products

While Epidiolex is the first actual cannabis-based drug to be approved by the FDA, three other synthetic cannabinoid products — Marinol, Syndros and Cesamet — have been approved for prescription use in the U.S. Marinol is a pill form of Dronabinol, a synthetically manufactured THC, while Syndros is an oral solution of the same compound. Cesamet is the brand name of another synthetic cannabis compound, Nabilone.

Marinol, marketed by AbbVie, has been approved to treat the loss of appetite (anorexia) in AIDS patients and to treat nausea and vomiting in patients receiving chemotherapy who have not responded to standard anti-nausea medicines. Marinol is a Schedule III controlled substance. Syndros, which is marketed by Insys Therapeutics for the same two indications, is a Schedule II controlled substance.

Cesamet (Nabilone), marketed by Bausch Health (formerly Valeant Pharmaceuticals), is used to treat nausea and vomiting in patients undergoing chemotherapy, and has also shown modest efficacy as a treatment for fibromyalgia. It is a Schedule II controlled substance. Nabilone was originally developed by Eli Lilly. The FDA approved the drug in 1985, but withdrew that approval in 1989. Valeant acquired the rights to Nabilone from Lilly in 2004 and obtained new approval from the FDA in 2006. Valeant also acquired the rights to market the product in the UK and the EU in 2007. Nabilone has been approved in Austria and Spain for the treatment of chemotherapy-induced nausea and in Belgium for the treatment of glaucoma, spasticity in multiple sclerosis, wasting due to AIDS, and chronic pain.

Further back in the pipeline, several cannabis drugs containing synthetic cannabinoids are in clinical trials.

Zynerba Pharmaceuticals (ZYNE) is conducting Phase II trials with a transdermal gel formulation of CBD to treat neuropsychiatric disorders, including Fragile X syndrome, a genetic condition in very young children that causes learning disabilities and cognitive

impairment. Zynerba is also studying CBD-derived drugs to treat autism spectrum disorder (ASD) in pediatric patients, a condition known as 22q or DiGeorge syndrome, and a group of rare epilepsies known as developmental and epileptic encephalopathies (DEE). 22q is a chromosomal disorder that results in the poor development of several body systems, which may include heart defects, poor immune system function, cleft palate, and low levels of calcium in the blood.

Corbus Pharmaceuticals (CRBP) is conducting Phase II trials of Lenabasum, a drug derived from THC, for the treatment of rare inflammatory diseases, such as systemic sclerosis, cystic fibrosis, and dermatomyotitis.

Building on its success with Epidiolex, GW Pharma plans to submit a New Drug Application to the FDA in 1H19 for Sativex, a cannabis-derived synthetic drug that treats spasticity in patients with multiple sclerosis. Sativex has already been approved in 25 countries, including several in the EU.

### Benefits from Regulatory Changes

As noted above, we expect the rescheduling of Epidiolex as a Schedule V controlled substance to make it easier for BPOS companies to participate in the development, manufacturing, and distribution of Epidiolex, and, by extension, other cannabis-based drugs. While cannabis remains a prohibited substance at the federal level under the Controlled Substances Act of 1970, a state-level “carve-out” was provided by the passage of the Rohrbacher-Farr Amendment in 2014. The amendment prohibits the Justice Department from spending funds in ways that interfere with state medical cannabis laws. In other words, in states that have legalized the medical use of cannabis, businesses can work on drug development and doctors can prescribe cannabis-based drugs.

Given the landmark advances for Epidiolex and the changing regulatory environment, we expect pharma companies to expand their efforts to develop cannabis compounds for additional therapeutic uses, both in the U.S. and overseas.

## APPENDIX

### Capstone Headwaters Life Sciences

#### Global BPOS Transaction Summary

September 1, 2018, to date

Transaction Date	Acquired/Investee	Acquiror/Investor	Transaction Value (\$ in 000s)	Acquired Industry Space
1/9/19	Boston Biomedical Associates	Factory-CRO Group	Not Disclosed	CRO
1/9/19	Ascendis Health facility	Mylan	\$9,400	CMO
1/2/19	Avista Pharma	Cambrex	\$252,000	Small-molecule API and finished dose form CDMO
12/18/18	Shire CMO facility	Rentschler Biopharma	Not Disclosed	Rare disease data compilation
12/12/18	WuXi AppTech	IPO	\$1,060,000	Drug research and development
12/5/18	PhyNexus	Biotage	\$21,500	Biomolecule purification
11/29/18	WuXi NextCODE	Genomics Medicine Ireland	Not Disclosed	Genome sequencing
11/26/18	Pola Pharma facilities	Sun Pharmaceuticals	\$1,000	CMO
11/18/18	KinderPharm	IPO	Not Disclosed	Pedicatric CRO
10/18/18	Clinical Network Services	Novotech	Not Disclosed	CRO
9/13/18	Sanoplasma	Shire	Not Disclosed	Plasma collection
9/12/18	DXS Clinical	WDB Medical Data	Not Disclosed	Provider of clinical development and data analytics services
9/12/18	Halo Pharma	Cambrex	\$425,000	Small-molecule API and finished dose form CDMO
9/4/18	Suono Bio	FujiFilm	Not Disclosed	Drug development technology

## TRANSACTION ATTRIBUTIONS

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# HIGHLIGHTS FROM RECENT RESULTS

## COMPILED BY ARGUS RESEARCH

### U.S. COMPANIES

#### BIO TECHNE (TECH)

##### Quarterly Results Summary

Bio Techne recently reported above-consensus results for fiscal 1Q19. For the quarter, sales grew 13% on a GAAP basis (10% organically) to \$163 million. The adjusted operating margin tightened by 140 basis points to 33.9%. Adjusted EPS rose 9% to \$0.98 and topped the consensus forecast of \$0.95. In fiscal 2018, sales grew 14% to \$643 million, and adjusted EPS rose 22% to \$4.54.

The company does not provide earnings guidance.

Segment	% of Sales	1Q19 Segment Growth Rate
Protein Sciences	78%	17%
Diagnostics/Genomics	22%	0.3%

##### Business & Customers — 1Q19 Transcript

- Protein Sciences posted strong organic growth in 1Q19 while the Diagnostics & Genomics segment was held back by the timing of OEM shipments; timing should become more favorable for the remainder of FY19.
- The company has averaged double-digit growth in Europe over the past two years; Europe was the first region to benefit from a unified selling model that combines reagents with instruments.
- Bio Techne also has a strong growth opportunity in China, which lacks comparable domestic life sciences suppliers.

##### Capital Strategy and M&A

- Two acquisitions (Quad Technologies and Exosome Diagnostics) were completed in 1Q19. Exosome Diagnostics provides exosome-derived diagnostics to detect numerous cancers and neurological conditions from body fluids, eliminating the need for invasive biopsies.
- Quad Technologies provides biocompatible dissolvable polymer (QuickGel) that captures and activates T-cells.
- In October 2018, Bio-Techne entered into a strategic cooperation agreement with Micropoint Bioscience in Shenzhen, China.

#### CAMBREX (CBM)

##### Quarterly Results Summary

Cambrex recently reported results for 3Q18. For the quarter, sales fell 7%, to \$105 million, or 8% in constant currency under ASC 606; revenue declined 9% under prior standard 605. Under ASC 606, EBITDA declined to \$15.8 million from \$33.7 million; excluding accounting-revision and Halo acquisition costs, adjusted EBITDA would have been \$28.1 million. Under ASC 606, adjusted EPS of \$0.79 rose 34% from the prior year.

Along with the 3Q results, management revised its 2018 revenue and adjusted EBITDA guidance. It now expects full-year 2018

adjusted net revenue, excluding the impact of currency translation and the change in accounting principles, to be down 3% to up 1% from 2017; earlier guidance had called for flat adjusted revenue at the midpoint of the range. Management has narrowed its adjusted EBITDA forecast to \$153-\$159 million from a prior \$150-\$160 million. This guidance does not include any impact from the Halo acquisition.

##### Business & Customers — 3Q18 Transcript

- The 3Q18 revenue decline matched expectations and reflected the adverse timing of certain project shipments. Excluding Halo, the company remains on track to reach its full-year EBITDA target.
- Halo adds finished-dose expertise to Cambrex's active pharmaceutical ingredient (API) leadership, thus strengthening its capabilities as an end-to-end small-molecule CDMO.
- With large pharma companies looking to reduce their small-molecule footprint, Cambrex has a robust and growing small-molecule clinical development pipeline.

##### Capital Strategy and M&A

- In 3Q18, Cambrex completed acquisition of Halo Pharma, a leading dosage-form CDMO, for \$425 million. Based on the timing of the deal, Halo will contribute for slightly more than one full quarter of 2018.
- In January 2019, the company acquired Avista Pharma Solutions from Ampersand Capital Partners for \$252 million. Avista expands Cambrex's BPOS business into early-stage small-molecule development and testing services.

#### CATALENT INC. (CTLT)

##### Quarterly Results Summary

Catalent recently reported above-consensus results for fiscal 1Q19. For the quarter, sales grew 1% (up 3% in constant currency) to \$552 million. Adjusted EBITDA rose 27% from the prior year and the adjusted EBITDA margin rose 410 basis points to 20.8%. Adjusted EPS increased 33% to \$0.28, in line with the consensus forecast.

For all of fiscal 2018, revenue of \$2.46 billion rose 19% as reported (16% organically) and adjusted EBITDA rose 22% to \$454 million.

For fiscal 2019, management reiterated its guidance calling for \$2.50-\$2.59 billion in revenue and \$597-\$622 million in adjusted EBITDA.

Segment	% of Sales	Q Segment Growth Rate
Softgel Technologies	36%	-6%
Biologics & Specialty Drug Delivery	28%	69%
Oral Drug Delivery Solutions	24%	-3%
Clinical Supply Services	14%	-29%

## HIGHLIGHTS FROM RECENT RESULTS (CONTINUED)

### COMPILED BY ARGUS RESEARCH

#### Business & Customers — 1Q19 Transcript

- The company's fiscal 1Q19 results modestly lagged expectations due to deal timing, with no implications for full-year guidance.
- Overall revenue growth was driven by the acquisitions of Juniper Pharmaceuticals and the Bloomington biologics business. Organic revenue fell 1%.
- The Softgel business continues to be hurt by a worldwide ibuprofen API shortage; Catalent is responding with efforts to optimize capacity across the Softgel network.

#### Capital Strategy and M&A

- In August 2018, Catalent completed the acquisition of Juniper Pharmaceuticals, a European provider of dose-form development and early-stage manufacturing services.
- Juniper builds on the 2017 Pharmatek acquisition and strengthens the company's offerings in formulations, bioavailability solutions, and clinical-scale oral dose manufacturing.
- In 1Q19, Catalent issued 1.4 million shares of common stock and used the proceeds to pay down \$450 million of U.S. dollar-denominated floating-rate debt.

## CHARLES RIVER LABS (CRL)

#### Quarterly Results Summary

Charles River Labs recently reported above-consensus results for 3Q18. For the quarter, sales grew 26% to \$585 million; excluding acquisitions and currency effects, organic sales grew 11%. The adjusted operating margin was flat with the prior year at 18.8%. Adjusted EPS rose 18% to \$1.53, above the consensus forecast of \$1.38.

Along with the 3Q results, the company updated its full-year outlook for 2018. It expects organic revenue growth of 8.0%-8.5%, up from a prior 7.0%-8.0%; GAAP revenue growth of 21%-22%, raised from 19%-21%; and adjusted EPS of \$5.87-\$5.97, narrowed from a prior range of \$5.85-\$6.00.

Segment	% of Sales	3Q Segment Growth Rate
Research Models & Services	22%	4%
Discovery & Safety Assessment	60%	43%
Manufacturing Support	18%	12%

#### Business & Customers — 3Q18 Transcript

- In 3Q18, Charles River reported double-digit organic revenue growth for the first time since 2008. The company is targeting long-term revenue growth in the high single digits.
- The strong third-quarter growth reflects a healthy market environment and the company's position as premier early-stage CRO able to support clients from the target discovery phase through nonclinical development.
- To enhance its speed and responsiveness, CRL has adopted a new operating model. Management believes that the new

model creates a more agile organization by accelerating decision-making and empowering unit leaders.

#### Capital Strategy and M&A

- The company's broad portfolio has been enhanced by the acquisitions of MPI Research, Brains On-Line, and KWS BioTest.
- To enhance its Discover & Safety Assessment business, Charles River recently signed an exclusive partnership with Distributed Bio. The partnership provides access to early-stage therapeutic antibody platforms that help to support clients' large-molecule discovery efforts.

## ICON PLC (ICLR)

#### Quarterly Results Summary

Icon recently reported in-line results for 3Q18. For the quarter, and excluding the adoption of ASC 606, sales grew 8% to \$476 million. GAAP revenue (including ASC 606) was \$55 million. The adjusted operating margin expanded by 140 basis points to 20.7%. Adjusted EPS increased 15% to \$1.55, in line with the consensus forecast.

Net book-to-bill (excluding ASC 606) was 1.27 for 3Q18; the "net business wins" ratio was 1.28; the closing backlog of \$5.28 billion was up 11% year-over-year.

#### Business & Customers — 3Q18 Transcript

- Net business awards of \$605 million in 3Q18 were an all-time record for the company. Customer concentration is diminishing, with Icon's top five customers (under ASC 606) accounting for 38.3% of total revenue.
- Management expects overall pharma R&D spending to grow 3% annually. It expects CRO industry revenue to increase at a faster 6% annual rate, as pharma companies outsource additional services.
- According to management, the CRO market increasingly favors larger CROs with a global footprint and a broad array of services, along with the patient access needed for complex clinical trials.
- Capital Strategy and M&A
- From the beginning of 2018 through the end of October, Icon repurchased \$92 million of its stock.
- Icon's ability to manage projects under various flexible outsourcing models is leading to new business opportunities.

## ILLUMINA INC (ILMN)

#### Quarterly Results Summary

Illumina recently reported above-consensus results for 3Q18. Third-quarter revenue rose 25.4% from the prior year to \$830 million. The non-GAAP operating margin rose 630 basis points to 28.4%. Adjusted EPS rose to \$1.43 from \$0.82 a year earlier and topped the consensus by \$0.26. For all of 2017, revenue rose 14.8% to \$2.75 billion and adjusted EPS rose 20.1% to \$4.00.

## HIGHLIGHTS FROM RECENT RESULTS (CONTINUED)

COMPILED BY ARGUS RESEARCH

Along with the 3Q results, management updated its full-year guidance for 2018. It continues to expect 20% revenue growth, but now looks for non-GAAP EPS of \$5.70-\$5.75, up from a prior \$5.35-\$5.45.

Segment	% of Sales	3Q Segment Growth Rate
Product	83%	22%
Service & Other	17%	21%

### Business & Customers — 2Q18 Transcript

- As a leading producer of next-generation sequencers (NGS), Illumina should benefit from the decision by the Centers for Medicare & Medicaid Services (CMS) to provide Medicare coverage for NGS testing of certain cancer patients.
- Illumina believes that it is less than halfway through a product transition cycle that will broaden its available market.
- Although 225 petabytes of sequencing data have been generated on Illumina platforms, less than 1% of the human genome has been mapped, signaling a vast opportunity for genetic sequencing equipment and services.

### Capital Strategy and M&A

- LunaDNA, funded partly by Illumina Ventures, has asked the SEC to approve its unique business model in which the company would provide stock-based compensation to individuals who upload their DNA. Researchers would then pay to access aggregate data stripped of personally identifying details.
- The “All of Us” program from U.S. National Institutes of Health and genomic programs in UK, Australia and other nations represent multiyear opportunities.

## IQVIA (IQV)

### Quarterly Results Summary

IQVIA recently reported above-consensus results for 3Q18. Third-quarter revenue of \$2.6 billion rose 5% on a reported basis and 6% in constant currency. Adjusted EBITDA rose 9% in constant currency, and the adjusted EBITDA margin expanded by 80 basis points to 21.6%. Adjusted EPS rose 19% to \$1.42 and beat the consensus by \$0.03.

Along with its 3Q results, management provided revised guidance for 2018. Under accounting standard ASC 606, the company expects 6.2%-6.7% revenue growth, to \$10.30-\$10.35 billion, raised from \$10.05-\$10.25 billion. IQVIA also guided for non-GAAP EPS growth of 19.8%-22.0%, raised from 17.6%-22.0%, and non-GAAP EPS of \$5.45-\$5.55, raised from \$5.35-\$5.55.

Segment	% of Sales	3Q Segment Growth Rate
Technology & Analytics	39%	13%
R&D Solutions	53%	3%
Contract Sales & Medical	8%	-13%

### Business & Customers — 3Q18 Transcript

- IQVIA continues to sign new clients to its Orchestrated Customer Engagement (OCE) platform. In mid-October 2018, it signed Roche Pharma to a multiyear OCE contract spanning more than 100 countries and 14,000 users.
- The IQVIA Technology & Analytics unit is benefiting from two significant contract wins with top-five pharma companies.
- Since launching OCE in December 2017, IQVIA has won 15 of 20 competitions in the OCE space.

### Capital Strategy and M&A

- IQVIA recently launched its Orchestrated Customer Engagement (OCE) SaaS offering, which uses artificial intelligence and machine learning to better integrate clients' commercial operations.
- IQVIA is also working with Salesforce.com on a new offering called Orchestrated Clinical Trials (OCT), which offers regulated content management, regulatory compliance, and virtual clinical trials.

## LABORATORY CORP OF AMERICAN HOLDINGS (LH)

### Quarterly Results Summary

Laboratory Corp. of America Holdings (LabCorp) recently reported above-consensus non-GAAP EPS for 3Q18. Third-quarter revenue of \$2.8 billion rose 8% from the prior year. Adjusted operating income of \$429 million fell 1%, and the adjusted operating margin narrowed by 130 basis points to 15.2%. Adjusted EPS of \$2.74 rose 16% from the prior year but missed the consensus forecast by \$0.14.

In November 2018, management trimmed its full-year guidance for 2018. With 2017 results recast to reflect the impact of accounting standard ASC 606, the company expects revenue growth of 9.9%-10.3%, reduced from 10.5%-11.5%, and non-GAAP EPS of \$10.95-\$11.05, reduced from \$11.35-\$11.65. It also lowered its full-year free cash flow forecast to \$940-\$980 million from \$975 million-\$1.025 billion.

Segment	% of Sales	3Q Segment Growth Rate
LabCorp Diagnostics	62%	0%
Covance Drug Development	38%	25%

### Business & Customers — 3Q18 Transcript

- LabCorp's 3Q18 performance was driven by Covance, which generated a 1.41 book-to-bill ratio and 130 basis points of margin expansion. On the negative side, the consumer (diagnostics) business was adversely impacted by Hurricane Florence and a ransomware attack.
- The reduction in guidance in November was solely attributable to challenges in the diagnostics business. LabCorp is making organizational changes to strengthen operating performance

## HIGHLIGHTS FROM RECENT RESULTS (CONTINUED)

### COMPILED BY ARGUS RESEARCH

in this business and accelerating the ramp-up of Phase II of its Diagnostics Launchpad.

#### Capital Strategy and M&A

- In 3Q18, the company completed the divestiture of Food Solutions at an attractive valuation.
- In October 2018, it announced plans to significantly expand the LabCorp-Walgreen collaboration from an initial 17 sites to at least 600 locations.
- In 4Q18 and beyond, LabCorp expects to deploy additional capital for share buybacks.

### MEDPACE HOLDINGS INC. (MEDP)

#### Quarterly Results Summary

Medpace Holdings (Medpace) recently reported above-consensus results for 3Q18. Third-quarter revenue of \$179 million under ASC 606 rose 82% from the prior year; under the prior standard of ASC 605, revenue of \$124 million increased 26% year-over-year. The adjusted EBITDA margin under ASC 606 was 20.3%; on an apples-to-apples basis under the prior ASC 605 standard, adjusted EBITDA of \$43 million (34.4% EBITDA margin) grew 52%. Adjusted EPS totaled \$1.13 under ASC 606; under ASC 605, adjusted EPS of \$0.80 rose 100% from the prior year. Adjusted earnings beat the consensus estimate by \$0.05.

Along with its 3Q results, management provided revised guidance for 2018 under the prior accounting standard ASC 605 in order to maintain comparability. Medpace expects net service revenue of \$474-\$479 million, raised from \$461-\$473 million; net service revenue growth of 22.7%-23.9%, up from 19.3%-22.4%; and non-GAAP EPS of \$2.76-\$2.82, up from \$2.51-\$2.62.

#### Business & Customers — 3Q18 Transcript

- Net new business awards (measured under ASC 605 for comparability purposes) rose 34% year-over-year in the third quarter. The net book-to-bill ratio was 1.22.
- The company faces the “significant” cancellation of an ongoing program with \$20 million in remaining unperformed service fees. Management expects the delayed timing of replacement revenue to be a headwind for several quarters.

#### Capital Strategy and M&A

- Medpace continues to expand its global infrastructure while engaging in business development activities. The company is hiring aggressively and expects to increase its headcount by about 20% in response to new business wins.
- Medpace did not receive any proceeds from a secondary offering of 5.2 million shares in August 2018. The selling shareholder was Cinven Capital Management.

### PRA HEALTH SCIENCES INC. (PRAH)

#### Quarterly Results Summary

PRA Health Sciences recently reported above-consensus non-

GAAP EPS for 3Q18. Third-quarter revenue of \$717 million under ASC 606 rose 23% (24% in constant currency); under the prior ASC 605 standard, revenue of \$573 million at actual exchange rates rose 8% organically. Adjusted EBITDA grew 30%, while the adjusted EBITDA margin (under ASC 606) expanded to 16.8% from 16.0% a year earlier. Adjusted net income of \$1.13 per share rose 28% year-over-year and beat the consensus by \$0.06.

Along with the 3Q results, management provided revised guidance for 2018. The company expects revenue of \$2.87-\$2.92 billion, trimmed at the high end from \$2.87-\$2.95 billion; under accounting standard ASC 606, the revised revenue estimate implies growth of 47%-50%; it also projects constant-currency organic growth of 18%-20%, raised from 10%-12%, and full-year non-GAAP EPS of \$4.22-\$4.27, raised from \$4.13-\$4.23.

#### Business & Customers — 3Q18 Transcript

- Net new business wins for 3Q18 rose 10% year-over-year, reflecting strong order trends and leading to a net book-to-bill ratio of 1.28.
- The backlog rose 4% sequentially and 20% from the prior year, finishing at approximately \$4.1 billion.

#### Capital Strategy and M&A

- The integration of Symphony Health, which closed in September 2017, is progressing as planned.
- PRA has a well-diversified client base, and new business awards continue to come 60% from pharmaceutical customers and 40% from biotech.
- In 2Q18, PRA amended its A/R financing agreement, which increased borrowing capacity and extended the maturity date.

### SYNEOS HEALTH INC. (SYNH)

#### Quarterly Results Summary

Syneos Health recently reported above-consensus non-GAAP EPS for 3Q18. Third-quarter revenue under ASC 606 was \$1.11 billion; under ASC 605, revenue of \$1.12 billion rose 8% from \$1.04 billion a year earlier. The adjusted EBITDA margin under ASC 605 increased 230 basis points to 20.4%, while adjusted EBITDA under ASC 605 of \$161 million rose 16%. Adjusted EPS under ASC 606 rose 43% year-over-year to \$0.77, and came in \$0.07 above the consensus forecast. For comparability purposes, adjusted 3Q18 EPS under ASC 605 was \$0.75.

Along with the 3Q results, the company provided an updated outlook for 2018. It expects revenue of \$4.375-\$4.435 billion, reduced from August guidance of \$4.40-\$4.55 billion, and adjusted EPS of \$2.66-\$2.80, versus earlier guidance of \$2.55-\$2.83.

Segment	% of Sales	3Q Segment Growth Rate
Combined Clinical Solutions	74%	8%
Combined Commercial Solutions	26%	8%

## HIGHLIGHTS FROM RECENT RESULTS (CONTINUED)

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### Business & Customers — 3Q18 Transcript

- Syneos, formed in August 2017 from the combination of InVentiv and INC Research, is seeing strong customer engagement based on the breadth of its biopharmaceutical outsourcing offerings.
- Solid sales execution resulted in total net new business awards of \$920 million in the third quarter. The book-to-bill ratio was 1.17 for the quarter and 1.21 for the year-to-date.

### Capital Strategy and M&A

- Syneos is carefully managing its capital structure while taking a balanced approach to capital deployment.
- Syneos is on track to achieve its 2018 merger synergy targets of \$65-\$70 million.
- In 3Q18, Syneos completed its acquisition of Kinapse, which expands its regulatory, safety, and pharmacovigilance consulting services in the post-approval space.

## THERMO FISHER SCIENTIFIC (TMO)

### Quarterly Results Summary

Thermo Fisher recently reported above-consensus non-GAAP earnings for 3Q18. Third-quarter revenue of \$5.9 billion grew 16% on a GAAP basis and 10% organically. Adjusted operating income grew 12% from the prior year, though the adjusted operating margin narrowed by 80 basis points to 22.1%. Adjusted EPS increased 13% to \$2.62 and topped the consensus forecast by \$0.07.

Management raised its full-year sales and EPS guidance for 2018 to reflect the company's strong operational performance, partly offset by less favorable currency effects. The company forecast revenue of \$23.99-\$24.09 billion, up from a prior \$23.7-\$23.9 billion; the revised guidance implies 15% annual revenue growth. Thermo also increased its full-year non-GAAP EPS guidance to \$11.00-\$11.06 from \$10.89-\$11.01; the new guidance implies 16%-17% growth.

Segment	% of Sales	3Q Segment Growth Rate
Life Sciences	25%	9%
Analytical Instruments	23%	12%
Specialty Diagnostics	15%	6%
Laboratory Products	42%	28%

### Business & Customers — 3Q18 Transcript

- Management noted that sales to pharmaceutical and biotech customers grew at a high-teens rate, while revenue from academic and government customers rose in the high single digits.
- Revenue from emerging markets and China grew more than 20%, driven by China's focus on improving public health, food safety, and the environment.
- In 2Q18, the company opened a Precision Medicine Science Center to help U.S. customers strengthen their capabilities in genomic, proteomic and metabolomic analysis.

### Capital Strategy and M&A

- In September 2018, the board authorized the repurchase of up to \$2 billion in TMO stock. There is no expiration date for the repurchase authorization.
- In October 2018, Thermo Fisher completed the purchase of Becton Dickinson's Advanced Bioprocessing business for \$477 million in cash. The acquisition adds complementary cell-culture media products and a strong technical services program, along with \$100 million in annualized revenue.

## FOREIGN COMPANIES

### DOTTIKON ES HOLDINGS AG (DESN)

#### Semiannual Results Summary

Switzerland-based Dottikon reports semiannually in Swiss Francs (CHF). Dottikon reported lower 1H18 revenue and net income. Net sales of CHF 56.6 million were down 19% from the prior year. Production output (net sales plus inventory changes in semifinished and finished goods) declined 11%. EBITDA of CHF 9.8 million fell 51% year-over-year. IFRS net income of CHF 2.0 million in 1H18 declined substantially from CHF 9.6 million a year earlier.

Along with the 1H18 results, management provided guidance for the full business year. Due to delayed net sales realization in the first half and despite a projected business recovery in the second half, the company now expects lower net sales and net income in FY18.

#### Business & Customers – 1H18

- Management attributed the company's disappointing first-half performance to geopolitical and economic uncertainties, the intermittent scale-up of business processes, and supply bottlenecks due to the enforcement of environmental regulations.
- Several Asian chemical producers were hurt by the temporary or permanent closure of facilities due to environmental issues, leading to disruptions in sourcing.

#### Capital Strategy and M&A

- Dottikon reaffirmed its focus on serving customers as a strategic development and manufacturing partner and its specialist role for hazardous reactions.

### EUROFINS SCIENTIFIC (ERF)

#### Semiannual Results Summary

Luxembourg-based Eurofins Scientific reports semiannually in euros. Eurofins reported 1H18 revenue of 1.74 billion euros, up 25% from the prior year. Revenue rose 5% on an organic basis. Core (non-IFRS) EBITDA grew 28% year-over-year and represented 18.4% of revenue. Core net income of 8.82 euros per diluted share rose 31% from the prior year.

## HIGHLIGHTS FROM RECENT RESULTS (CONTINUED)

### COMPILED BY ARGUS RESEARCH

Along with the 1H18 results, management expressed confidence that it would achieve its full-year objectives. The company forecast revenue of 3.8 billion euros (4 billion euros on a pro forma basis) for 2018, 4.39 billion euros for 2019, and 4.7 billion euros for 2020. The company continues to target a core EBITDA margin of 20% by 2020.

#### Business & Customers — 1H18

- Eurofins has doubled revenue more than three times between 2005 and 2017 and grown EBITDA more than twelvefold during this period.
- Eurofins' services across four platforms (food, environment, clinical, and pharmaceutical) have high barriers to entry. The company's bioanalytical business is highly scalable and benefits from a global network of laboratories.
- The company is halfway through its current five-year growth plan, with the goal of building a one-of-a-kind laboratory infrastructure platform.

#### EVOTECH AG (EVT)

##### Semiannual Results Summary

Germany-based Evotech reports semiannually in euros. Evotech reported 1H18 revenue of 174 million euros, which was up 67% from the prior year. Core (non-IFRS) EBITDA grew 47% and represented 22.2% of revenue. IFRS net income of 0.12 euros per diluted share rose 71% from the prior-year quarter.

Along with the 1H18 results, management provided guidance for 2H18. Group revenues are expected to increase at least 30% year-over-year. Adjusted EBITDA is also forecast to grow approximately 30%.

#### Business & Customers – 1H18

- Evotech acquired Aptuit in August 2017 and Evotech ID SAS in July 2018.
- The company has strengthened its partnership with Celgene in oncology, and in September 2018 expanded this partnership to include targeted protein degradation.

#### LONZA GROUP (LONN)

##### Semiannual Results Summary

Switzerland-based Lonza Group reports semiannually in Swiss Francs (CHF). Lonza reported 1H18 revenue of CHF 3.08 billion, which was up 33% from the prior year. Excluding Capsugel, revenue rose 8% in constant currency. Core (non-IFRS) EBIT grew 42.3% (12.4% in constant currency and ex-Capsugel). Core net income of CHF 6.56 per diluted share rose 33% year-over-year. For all of 2017, revenue for standalone Lonza rose 10.4% to CHF 4.56 billion. Including results from the Capsugel acquisition, revenue of CHF 5.11 billion rose 23.5%; core (non-IFRS) EBITDA of CHF 1.27 billion rose 37.8%; and core basic EPS of CHF 11.84 rose 51.6%.

Along with the 1H18 results, management provided full-year guidance. The company expects mid- to high single-digit revenue growth, up from its earlier guidance of mid-single-digit growth on a comparable basis. It expects a full-year core EBITDA margin in line with the 1H18 core EBITDA margin of 26%.

Segment	% of Sales	1H Segment Growth Rate
Pharma&Biotech	51%	51%
Specialty Ingredients	49%	20%

#### SIEGFRIED HOLDINGS AG (SFZN)

##### Semiannual Results Summary

Switzerland-based Siegfried Holdings AG reports semiannually in Swiss Francs (CHF). Siegfried Holdings reported 1H18 revenue of CHF 377 million, which was up 8% from the prior year (5% in local currency). EBITDA rose 20%, and the EBITDA margin widened by 160 basis points to 16.8%. IFRS net income of CHF 29.3 million rose 35.5% from the prior year. For all of 2017, revenue increased 4.6% to CHF 750 million; EBITDA of CHF 114 million rose 17.9% and diluted EPS of CHF 9.71 rose 38%.

Along with its 1H18 results, management provided full-year guidance for 2018. It expects at least mid- to high single-digit revenue growth at constant exchange rates and a wider EBITDA margin.

Segment	% of Sales	1H Segment Growth Rate
Drug Substances	74%	6%
Drug Products	26%	15%

# HIGHLIGHTS FROM RECENT RESULTS (CONTINUED)

COMPILED BY ARGUS RESEARCH

## BPOS VALUATION TABLE

	Ticker	Fundamentals				Growth Rates				Valuations			
		Mkt. Cap (\$BIL)	Revenue (\$BIL)	Op Mgn (%)	D/E (%)	Rev %	EPS %	1-Yr Return (%)	5-Yr Return (%)	PS	PE	EV/EBITDA	Yield (%)
<b>US Companies</b>													
Bio-Techne Corp.	TECH	5.5	0.7	33.9	51	11	15	7	53	8.4	44.0	28.8	0.9
Cambrex Corp.	CBM	1.4	0.6	24.8	49	3	-6	-16	129	2.4	14.1	8.6	0.0
Catalent Inc.	CTLT	4.6	2.5	12.2	149	2	3	-23	61	1.9	15.8	12.8	0.0
Charles River Laboratories International, Inc.	CRL	5.4	2.3	15.9	132	21	13	1	93	2.5	17.6	14.0	0.0
ICON Public Limited Company	ICLR	6.7	2.6	15.9	26	47	13	6	200	2.9	18.3	15.3	0.0
Illumina Inc.	ILMN	45.5	3.3	28.2	52	21	44	33	159	14.1	48.7	39.5	0.0
Iqvia Holdings Inc.	IQV	23.2	10.3	9.6	142	28	18	19	141	2.7	18.7	18.2	0.0
Laboratory Corporation of America Holdings	LH	12.8	11.3	14.3	89	11	15	-24	39	1.1	11.2	8.8	0.0
Medpace Holdings Inc.	MEDP	2.0	0.7	14.0	25	81	65	62	99	3.2	19.4	15.4	0.0
PRA Health Sciences Inc.	PRAH	6.1	2.8	12.0	122	43	28	11	366	2.5	19.2	16.7	0.0
Syneos Health Inc.	SYNH	4.7	4.4	5.1	102	138	20	11	103	1.2	14.6	21.8	0.0
Thermo Fisher Scientific Inc.	TMO	94.0	24.0	15.3	70.0	15	16	15	94	3.9	19.0	18.1	0.3
<i>Averages</i>		<i>17.7</i>	<i>5.5</i>	<i>16.8</i>	<i>84.0</i>	<i>35</i>	<i>20</i>	<i>9</i>	<i>128</i>	<i>3.9</i>	<i>21.7</i>	<i>18.2</i>	<i>0.1</i>
<b>Foreign Companies</b>													
Dottikon ES Holding AG	DESN	0.6	0.2	19.5	NA			-47	79	3.5	39.0	10.8	0.0
Eurofins Scientific	ERF	6.3	3.8	11.1	86	27		-34	126	1.9	34.0	12.4	0.8
Evotech AG	EVT	2.9	0.4	16.9	38	40	125	41	388	8.2	47.0	28.0	NA
Lonza Group Ltd.	LONN	21.2						6	440		27.0		NA
Siegfried Holding AG	SFZN	1.6	0.8	8.7	11	8	35	14	124	2.0	32.0	12.3	NA

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