

*Service Member Spotlight*  
**Porzio Life Sciences**



Porzio advances the life sciences industry by delivering the highest quality services and technology solutions to support healthcare compliance across business operations. We collaborate with our clients to bring tailored, pragmatic resolutions to their specific operational needs. We apply our passion, determination and creativity to streamline clients' commercial and compliance processes, so they can apply their passion to improving the health of patients, supporting the global healthcare community and developing innovative products.

Since its inception in 2004, PorzioLS has grown to offer a varied portfolio of compliance tools and services related to the laws of the 50 states, the District of Columbia and the federal government, and transparency and data privacy-related services pursuant to laws, regulations and industry codes around the world. PorzioLS has provided compliance and regulatory services to approximately 400 life sciences companies, including nine of the top ten global pharmaceutical companies.

***Experience & Capabilities Overview: HCP/HCO Transparency Services***

PorzioLS provides a complete range of aggregate spend and transparency-related services to the life sciences industry, including audits, gap assessments, program development, data management and remediation, report preparation and submission, dispute resolution and fully automated end-to-end solutions. We have provided HCP/HCO transparency reporting services to large, mid-sized and small pharmaceutical, medical device and bio-technology companies based in North America, Europe and Asia. We currently serve approximately 100 life sciences companies within our transparency and HCP interaction ecosystem.

PorzioLS also offers a full range of services to assist companies with internal management of transparency operations, including:

**Audits:** PorzioLS performs audits of life sciences companies' HCP/HCO interactions, transparency processes and transparency reports to ensure compliance with governing laws, regulations and company policies. Audits include process reviews, as well as accuracy testing, classification testing, completeness testing and cut-off testing.

**Gap Assessments:** PorzioLS conducts assessments of current and anticipated activities and interactions related to transparency compliance. These services include: meetings with various business units and vendors; reviewing existing transparency-related policies and procedures, contract language, etc.; and assessing existing

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**In Brief...**

- ◆ **AmerisourceBergen** reported revenues of US\$43.1 billion for the third quarter ended June 30th, an increase of 11.5% year-over-year. The reported figures reflect an 11.6% increase in Pharmaceutical Distribution and an 8.8% increase within other business units (AmerisourceBergen Consulting Services, World Courier, and MWI Animal Health.) Net income was US\$276 million with a diluted eps up 7.7% to US\$1.54 for the quarter, due mainly to the reduction in the U.S. federal income tax rate from 35% to 21%. Consolidation of **Profarma** and the acquisition of **H.D. Smith** were primary drivers for revenue growth as well.

- ◆ **Cardinal Health** reported for the fourth quarter fiscal 2018, with revenues of US\$35 billion, a 7% increase year-over-year. Fiscal year 2018 revenues were US\$137 billion, an increase of 5% from fiscal 2017. Fourth quarter net earnings came in at US\$315 million, down 24% from the previous year. The company reported FY2018 earnings of US\$1.6 billion, down 9% from 2017. Fourth quarter revenue for the pharmaceutical segment increased 6% to US\$31 billion due to sales growth from Pharmaceutical and Specialty Distribution customers, and partially offset by the divestiture of the company's China distribution business and expiration of the large mail order customer contract, both of which were previously announced.

- ◆ **Express Scripts** announced exclusion of 48 drugs from its national preferred formulary for 2019, hitting **AbbVie**, **Gilead**, **Boehringer Ingelheim** and others. Twenty-two of these drugs

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**Consolidation and Integration within the CEE Markets**

*Source: An article published by Fitch Solutions*

Within the Central and Eastern European (CEE) region, the pharmaceutical supply chain is relatively fragmented. However, in recent years there has been a significant shift in the wholesale and retail competitive landscape, with a notable uptick in consolidation and vertical integration.

The Fitch Solutions' article highlights the trend, using the activities of the Phoenix Group and the Penta Investment Group to illustrate. Both organizations have acquired smaller players within both the wholesale and retail sectors to create an integrated network of market leaders across the region.

The Phoenix Group is one of the largest pan-European medicine distribution networks, active in 26 countries. Under its Benu pharmacy chain brand, it is one of the dominant players in the pharmaceutical retail sector across the CEE region, with more than 1,200 pharmacies in 10 countries. Since its inception in 2012, Benu has gradually expanded throughout the region through the acquisition of smaller players, such as its November 2017 purchase of Serbian pharmacy chain Goodwill and its 2016 acquisition of

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internal and external data sources and data collection templates.

*Data Management:* PorzioLS helps companies manage the data collection, review and remediation processes. Our teams use their extensive knowledge and experience to facilitate: spend and sample data corrections; business solutions for data capture and remediation; recipient, nature and purpose type value mapping to the corresponding jurisdictional values; preparation of assumptions documents; data auditing and monitoring; and internal personnel training.

*Report Management:* PorzioLS helps companies to manage the processes for generating, reviewing, approving and submitting aggregate spend and transparency disclosure reports. These services include: identification of reportable spend types; assessments to identify jurisdictions in which a company has reporting obligations; collection and standardization of data to identify gaps and inconsistencies; investigation into missing or invalid data elements; preparation and quality control review of draft reports; and report submission requirements and processes.

*Project Management:* PorzioLS offers project management services to support our customers' internal end-to-end aggregate spend and transparency processes. These services include working with business units and vendors to establish processes for data collection and delivery; preparing templates for data collection; obtaining the data necessary for aggregate spend reporting; responding to day-to-day regulatory questions from customer and vendor personnel; assisting customers with preparing annual aggregate spend registration forms; and generating and reviewing reports that comport with the template in each jurisdiction.

*Manual Reporting Services:* As an alternative to our fully automated Platform, PorzioLS, in conjunction with MedPro Systems, LLC, offers manual reporting services to support our customers' transparency obligations when they are limited due to data volumes, geographic footprint, newly commercialized products and emerging regulatory landscapes.

*Training:* PorzioLS provides general compliance training services to life sciences companies on a variety of topics, including: general compliance; aggregate spend and transparency compliance; company policies and SOPs; and data collection requirements and best practices.

*Global Privacy Assessments:* PorzioLS conducts data privacy GAP assessments for companies, whereby we investigate their current and anticipated activities and interactions as they relate to the collection, use, processing, storage, and transfer of personal information and data. After conducting such assessments, PorzioLS provides recommendations on internal compliance and business processes as part of educating the company on privacy issues and assisting with the development of a privacy action plan.

*General Consulting:* Consulting services are provided on a wide range of regulatory and compliance issues, from policy, procedure and work instruction development, to reporting and data services, to global transparency risk assessment and mitigation.

### **Transparency Reporting Solutions**

Through the joint venture between PorzioLS and MedPro, PorzioLS and MedPro launched *Porzio AggregateSpendID* in July 2010. Porzio AggregateSpendID is a true “end-to-end,” fully hosted, web-based aggregate spend tool that allows life sciences

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Slovakian Sunpharma. In February 2017, the firm expanded into its tenth market within the CEE region, Montenegro. Phoenix also owns two pharmacy chains outside of the CEE, Apotek 1 (Norway) and Rowlands Pharmacy (UK).

The Phoenix Group's pharmaceutical wholesale business supplies approximately 53,000 pharmacies and medical institutions across the European region through its 154 distribution centers. It owns market leading distribution firms in countries across the region as well its own brand wholesale company.

In March 2017, the Group opened a new logistics and distribution center in Serbia to form part of a new cross-border solution called the “CEE Bridge” alongside logistics hubs in the Czech Republic and Poland. The hub in Serbia will enable Phoenix more efficiently serve the 17 million citizens in Bosnia-Herzegovina, Macedonia, Serbia, Montenegro, Albania and Kosovo. Further, the CEE Bridge enables the firm to provide the required pharmaceutical wholesale and logistics services to manufacturers and retailers across the region.

The Phoenix Group also coordinates the cooperation of 12 locally well-established independent pharmacy chains across 15 countries under its Phoenix Pharmacy Partnership program. It claims this benefits drugmakers by providing simple and fast market access in a more cost-efficient manner.

The Penta Investment Group owns the Dr Max pharmacy chain, the largest network of independent pharmacies in the Czech Republic, Slovakia and Poland. The Dr Max chain has progressively expanded its presence in these core markets through the acquisition of market competitors, such as the 2013 purchase of the Mediq Apteka pharmacy chain in Poland, making it the second largest pharmacy chain in the country, and the acquisition of 55 Lloyds pharmacies in 2012 from McKesson Europe (formerly Celesio) in the Czech Republic in 2012.

It has also sought to expand its presence within the wholesale sector. Penta owns the second-largest wholesaler in the Czech market, ViaPharma, which was acquired from German Gehe Pharma, a subsidiary of McKesson Europe, in 2012.

In recent years, the chain has sought to expand its presence outside of its core Central European base. In 2017, it acquired two Serbian pharmacy chains, Farmanea and Farmakop. In June 2017, Dr Max entered into the Romanian market with the acquisition of the Arta pharmacies chain, consisting of 31 pharmacies. In December 2017, Dr Max entered into an agreement to acquire Romanian A&D Pharma. A&D Pharma owns the Sensiblu and Punkt pharmacy networks, the Mediplus wholesale company and A&D Marketing and Sales, one of the biggest pharmaceutical marketing and sales platforms in the CEE region. Because of this transaction, Dr Max will become a major player in the Romanian market, with 613 pharmacies. After this acquisition, Dr. Max now operates approximately 2,000 pharmacies across the CEE region, with 12,000 employees and revenues of EUR2.3bn (US\$2.7bn).

The acquisition of A&D highlights Penta's aim to expand its presence as a major regional player within both wholesale and retail sectors of the pharmaceutical distribution chain. Commenting on the acquisition, Dr Max's CEO Leonardo Ferrandino stated, “with the acquisition of A&D Pharma, Dr Max is further strengthening its presence in Central Europe and is clearly expanding its leading position as an Omnichannel retail healthcare provider in Europe.”

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companies to capture, review, track and report interactions with US-based HCPs and HCOs. Porzio AggregateSpendID incorporates US-validated HCP data sources (e.g., National Plan and Provider Enumeration System, State Boards of Medicine, Nursing, Pharmacy, CMS's Validated Physicians List) into its data processing and validation schema that are necessary to comport with the highly regulated US transparency landscape. Product development, implementation, and ongoing customer support services are all provided jointly by PorzioLS and MedPro team members. Together, PorzioLS and MedPro have successfully implemented Porzio AggregateSpendID in over 70 companies and, in 2018 supported the successful submission of Open Payments reports by 67 companies. Moreover, in 2018 Porzio AggregateSpendID was responsible for the aggregation and reporting of 17% of all General and Research Payments transactions reported through the Federal Open Payments program.

Most recently, PorzioLS leveraged its extensive regulatory and operations experience related to US transparency and Sunshine Act requirements to build Porzio GST. Porzio GST is an “end-to-end,” fully hosted, web-based HCP management and transparency reporting solution that allows life sciences companies to capture, review and track interactions with HCPs and HCOs across the globe and report on interactions with HCPs pursuant to current requirements in Europe (including EFPIA), Australia and Japan. Porzio GST is designed to address data privacy, cross-border, currency, character set and language challenges, as well as the ever-evolving landscape of report formats. PorzioLS has provided EU, EFPIA, Australia and Japan transparency consulting and reporting services to the life sciences industry for over 5 years, and currently works with two mid-size multi-national companies to support their European, EFPIA and Australian reporting obligations via Porzio GST. In addition to Porzio GST, PorzioLS currently provides global transparency counseling and manual reporting services to 13 companies.

Together, Porzio AggregateSpendID and Porzio GST form our Global Transparency Platform ("Platform"). Porzio AggregateSpendID and Porzio GST are seamlessly integrated to complement each other and provide a full, flexible and nimble world-wide reporting and monitoring platform. Offering a global Platform with two specialized components allows us to safeguard system integrity while maximizing the efficiency and effectiveness of each of their specialized functions. Together, these integrated solutions form the Platform from which we serve our global customer base.

On behalf of 67 companies, in 2018 our Platform generated over 300 US federal, state and local reports and 60 EFPIA and other European and Australian reports. Each of these reports was successfully uploaded, posted and attested to (as necessary) by our customers.

*For further information, contact Frank Fazio at [fazio@porziols.com](mailto:fazio@porziols.com). He will also be attending the IFPW 2018 General Membership Meeting October 10-12th in Washington D.C. To schedule some time with Mr. Fazio during the meeting to discuss how Porzio can assist your organization, please email or call (in the U.S.) (973) 538-1690.*

## In Brief (cont.)...

compete against generics, 12 of whose rivals use the same active ingredient at a lower net cost, and 11 that bear cheaper brand or biosimilar alternatives. The Express Scripts website posted “Despite promises to limit price increases, drug makers are trying to game the market by delaying generic competition, blocking access to safe and effective biosimilars, and coyly deferring—if not cancelling—list-price increases.”

◆ McKesson named *Brian Tyler* as president and COO. Tyler will report directly to *John Hambergren* and serve as a member of the executive committee. “Brian is ideally suited to lead McKesson’s global operations based on his deep industry knowledge, outstanding track record as a business leader, and his commitment to operational excellence and customer,” said John Hambergren in a press statement. Tyler previously served as Chairman of the Management Board for McKesson EU.

◆ The **National Association of Chain Drug Stores** (NACDS) has submitted comments on drug pricing public policy issues to Health and Human Services secretary Alex Azar in response to the agency’s request. “We believe there are numerous opportunities to achieve the goals of lowering the financial burdens on patients and making prescription drugs more affordable and accessible,” wrote NACDS President, *Steve Anderson*. “However, we caution HHS that policy proposals to achieve these goals should also ensure patient access to their prescription medications and critical pharmacy services.”

◆ In a report produced by **IQVIA** for the **Association for Accessible Medicines**, 93% of generic prescriptions are filled for US\$20 or less, with the average co-pay coming in at just US\$6.06. The *Generic and Savings Report in the United States 2018* used data collected in 2017, which also showed that generic medicines account for 9 out of 10 prescriptions filled in the United States.

◆ **Amgen** announced that *Sean E. Harper, M.D* will step down from his position as executive vice president of research and development. Additionally, *Anthony C. Hooper* will also leave his position as executive vice president of global commercial operations. *David M. Reese, M.D.* will replace Harper while *Murdo Gordon*, currently chief commercial officer, will assume the position of executive vice president of commercial operations.

◆ Thousands of Korean pharmacists braved sweltering temps in excess of 37 degrees Celsius to protest the sale of over-the-counter (OTC) drugs at convenience stores as well as demanding public night-time pharmacies. The rally, held in Cheonggye Plaza in central Seoul, was organized by the **Korean Pharmaceutical Association (KPA)**.

◆ **CVS Health’s** retail **MinuteClinics** launched telehealth video visits, allowing for patients to interact directly with healthcare providers through video visits. Patients with issues such as skin conditions, minor illnesses and injuries, and other wellness needs will have access to healthcare services 24 hours a day, seven days a week from their mobile device, the company announced. In a study by CVS Health, 95% of patients who opted to receive a telehealth visit were overwhelmingly satisfied with the overall experience.

*(Sources: Company Press Releases, Drug Store News, FiercePharma, and Korea Biomedical Review)*