A mix of recent reforms and international opportunity has emboldened China-based IVD suppliers, ushering in a wave of higher-profile, globally-minded, and better-capitalized Chinese players. Hrishi Poola, Jon Chen and Yi Ling Dai of Boston Biomedical Consultants take a look at the driving forces behind this trend and what will be expected from Chinese exhibitors at one of the year’s key IVD events, the annual meeting of the American Association of Clinical Chemistry (AACC).

Today, most China IVD companies remain small in scale, with only a dozen generating over $50m in annual sales (from self-made and distributed IVD products). However, local players increasingly seek a foothold in the international market and go upmarket through higher-capacity product launches, broader portfolios, and partnerships with global players.

China companies have diversified beyond their traditional offerings of clinical chemistry, three-part differential hematology semi-automated systems, and ELISA/MTP solutions. Instead, they have moved into higher-capacity clinical chemistry and chemiluminescence immunoassay (CLIA) systems, integrated chemistry/CLIA platforms (e.g., Mindray Medical), more five-part differential hematology systems, point-of-care solutions with broadening menus, and molecular diagnostic products. Despite their growing sophistication, China-developed products lag far behind those of global manufacturers and claim limited presence in higher-volume “top-tier” sites. To thrive in developed markets, local players must pass significant competitive, adoption, and quality hurdles.

Recently, sweeping reimbursement, procurement, regulatory and public financing reforms, aimed at raising local manufacturers’ competitiveness, have strengthened the positioning of Chinese supplier both at home and abroad. An overhaul of the National Medical Service Fee Schedule Guidelines, first announced by the National Health and Family Planning...
Commission (NHFPC) (formerly Ministry of Health) in 2012, began implementation in early 2014. The reform largely harmonizes reimbursement, prohibiting differential pricing based on technology, such as that between CLIA and ELISA methods, and product origin, such as that between multinational companies (MNCs) and local China suppliers. Only select local governments, including Shanghai and Zhejiang, have announced a partial remake of existing medical service fee schedules, with most provinces missing the December 2013 deadline for publishing 2014 schedules. Whether in full or partial compliance, new fee schedules will strengthen local company positioning and weaken the pricing premium advantage for MNCs.

Public procurement reform is also underway. In June 2014, the NHFPC initiated the creation of a product catalogue of high-end China-made medical equipment as a reference for procurement by all health care and family planning organizations in China. The evaluation process in the first half of 2014 involved digital X-ray devices, ultrasound systems, and clinical chemistry systems and will expand to other types of medical devices and diagnostic products. As an official reference for nationwide procurement deals, the proposed catalogue will further strengthen the competitive edge of large and established domestic players, including Dirui, Landwind, Mindray, Kehua, SNIBE, and others.

Additionally, in February 2014, the China Food and Drug Administration (CFDA) announced new medical device regulations, effective 1 March 2014, provisioning fast-track approval of new and innovative domestic products (eg DaAn Gene’s next-generation sequencing Down’s syndrome test kit). In March 2014, the State Council released amended regulations allowing companies to apply for marketing authorization without first obtaining a device manufacturing permit, provided that the relevant GMP requirements are fully in compliance during product design and development. This change will help R&D-based device companies save substantial investments in manufacturing facilities.

Lastly, the first half of 2014 saw a flurry of IPO activity after the Chinese Securities and Regulatory Commission (CSRC) resumed its IPO application reviews late last year. China-based manufacturers have been seeking capital through second-round financing and IPO registration in an effort to fund geographic and product line expansion, as well as diversification into higher-growth segments (eg, CLIA, molecular diagnostics). Between April and June 2014, eight China-based IVD companies, AutoBio, Health BioMed, Maker, Ningbo Medical System, Runda, Strong Biotechnologies, Thalysis, and Wondfo were among nearly 50 healthcare/medical product companies that announced pre-IPO disclosures. Of the top 20 China IVD manufacturers by total revenue (including distribution sales), over 70% are currently listed on the mainland China and overseas stock exchanges or are in various stages of the IPO process (Table 1).

That said, despite signals of freer capital, several IVD companies have faced difficulty passing the IPO gauntlet. Additionally, another hurdle has come up— in July, the CSRC once again suspended review of most IPO candidates, disrupting public financing efforts. This stop-start of CSRC’s activities which slows down the review/approval process is likely due primarily to out-of-date financial disclosures and incomplete filings it is receiving from the prospectus issuers. The commission may also want to limit the number of IPOs to 100 (out of nearly 640 on the waiting list) for the second half of 2014.

China’s rise at AACC 2014

The American Association of Clinical Chemistry Annual Meeting (AACC) & Clinical Lab Expo (CLE) is a key global conference for the IVD industry. This year’s AACC & CLE will take place on 27-31 July in Chicago, Illinois, and will feature a record 98 China exhibitors, up from 71 last year. The exhibitors will showcase a mix of IVD products (Figure 1) and related accessories and medical supplies (eg, blood collection tubes, source reagents, laboratory consumables and apparatus), as well as professional services. While most China exhibitors will maintain a low profile, several, including Mindray and SNIBE, will expand their floor presence. New IVD participants will include Genius, Getein, Sinnova, Tecom, and Unidiag; absent from the event will be Autobio, Corman, Encode, Lining Bio-Products, and Maxcom. Few new system debuts are expected, aside from Mindray’s OmniLab CAL 8000 hematology line and SNIBE’s MAGLUMI 800 CLIA analyzer. Clinical chemistry, coagulation, hematology, microbiology, molecular, rapid/POC, and urinalysis offerings will be on display, among others (Figure 2).

Dirui will showcase its full line-up of clinical chemistry, hematology, and urinalysis systems. The centerpiece will be the CS 6400, a modular clinical chemistry system featuring a throughput ranging from 1,600 to 6,400 photometric tests per hour. Marking the company’s entry path into North America, Carolina Liquid
Chemistries will debut the CLC6410 clinical chemistry analyzer, OEM from Dirui. Rounding out the exhibit will be Dirui’s FUS series urinalysis systems, including the FUS-2000 integrated urine chemistry/sedimentation workstation, and BF series hematology systems. The company continues to evaluate new product line expansion and continues to pursue an IPO.

Maker, the largest IVD manufacturer in southeast China, will promote its IS 1200 CLIA analyzer, offering a throughput of 120 tests per hour and a menu of over 60 assays, including new TORCH and thyroid parameters. In April 2014, the company filed an IPO prospectus; through the IPO, Maker expects to raise $59m largely to fund R&D and production expansion.

Mindray will once again draw significant attention, promoting its growing IVD portfolio under its new campaign “Medical Minds Think Alike.” The company’s global IVD sales topped $330m in 2013, with a growing proportion generated outside of China. Spotlight will fall on the new OmniLab CAL scalable hematology track, featuring the CellDiff BCM 2 (Cellavision), the BC 6800 hematology analyzer, and the SC 120 slidemaker stainer, as well as the OmniLab SAL 8000, Mindray’s first integrated chemistry/CLIA system comprised of the BS 2000M chemistry module and the CL 2000i immunoassay system.

Earlier this year, Mindray unveiled its first flow cytometer, the BriCyte E6, slated to launch in China in 2014. The company will also display its other chemistry, hematology, coagulation, microbiology, and urinalysis offerings.

SNIBE boasts over 3,000 users in over 90 countries worldwide and is the leader in the China CLIA market in absolute installed base. The company will promote its MAGLUMI family of CLIA systems, ranging from 120 to 280 tests per hour. New will be the MAGLUMI 800, which launched in China in early 2014 and offers a throughput of 180 tests per hour. The IBE 6000 integrated chemistry/CLIA system, pending CFDA approval, will be absent. The company will spotlight its broad and growing assay menu of over 100 parameters, including new additions Chagas, Hepatitis A, and HTLV.

Other notable exhibiting companies include Coyote Bioscience, which will display its Mini8 and Theater Slim PCR cyclers; the company continues to develop a “one step” POC molecular system. Edan Diagnostics will spotlight its i15 cartridge-based POC blood gas/chemistry analyzer and its DS-500/600i five-part differential hematology systems. Fosun, in addition to highlighting its new PCR companion diagnostic tests, will share a booth with its German partner micom diagnostics to promote the latter’s multiplex molecular sepsis and respiratory assays. InTec, a leader in infectious disease and rapid-based testing, will also feature its ABO and RhD blood grouping and typing test cards; the company continues to develop an automated blood grouping and typing instrument. URIT, which will showcase its full range of clinical chemistry, hematology, and urinalysis systems, will highlight its new urinalysis workstation integrating the URIT-1600 urine chemistry and URIT-1280 sedimentation analyzers.

**Beyond China: the promise and challenge**

MNCs have already felt the early ripples as China suppliers branch out, first in Asia-Pacific, Eastern Europe, Latin America, and Middle East/Africa markets, with an eye on Western Europe and North America in the medium to long term. However, despite their ambitions and improving product quality and breadth, China manufacturers face significant barriers in developed regions, including the established presence of MNCs, having to meet the high bar set for product quality/service, intensifying regulatory pressure, and the importance of established distribution channels. Furthermore, seasoned MNCs continue to invest in next-generation assays, biomarker discovery, and higher-capacity platforms. China-developed products still require significant, rigorous comparative performance studies in order to compete with “best-in-class” products. Despite myriad challenges, China companies have staked their aspirations and are clearly vested in opportunities beyond China. The future will reveal their success on the world stage.

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