DSM (Heerlen, the Netherlands) announced that it is moving ahead with the construction of a commercial-scale biomanufacturing facility in Montreal, Canada. The new facility will adjoin the existing DSM Biologics facility in Montreal. The building’s design will incorporate four bioreactors for mammalian-cell culture, with a total capacity of 60,000 L, and full downstream processing capabilities.

The plant is being built in two phases. The first phase includes the building and all necessary infrastructure to support the four bioreactor operations, but only two 15,000-L units will be installed. This phase will cost a little more than $100 million and is expected to be on stream by mid-2005. No target date has been set for the second phase, which will add another 30,000 L of capacity.

The Société Générale de Financement du Québec (SGF), a quasi-governmental agency, will finance 40% of the investment. SGF helped finance the original DSM Biologics facility in Montreal and is part-owner of the enterprise.

The DSM investment represents the largest commitment to new cell-culture capacity since Lonza (Zurich, Switzerland) announced its plan to build 60,000 L (3 × 20,000 L) of capacity at its Portsmouth, New Hampshire, location two years ago. Lonza’s manufacturing capacity is expected to come on-line in mid-2004 and is already 90% committed following a large-scale monoclonal antibody supply agreement that was signed in May 2003 with an unnamed top-10 pharma company.

Another major contractor adding cell-culture capacity is Diosynth, whose new facility in Oss, the Netherlands, will house an 18,000-L bioreactor. Among other major contract biomanufacturers, Avebia (Manchester, UK) has focused on new microbial capacity, and Dow Chemical (Midland, MI) seems to be holding off on new capacity commitments at its Rhode Island facility.

Controlling the availability of contract mammalian-cell culture capacity is a challenge. Companies are moving in and out of the market as their strategies or in-house capacity requirements change. Sponsors with excess capacity, including GlaxoSmithKline (Brentford, UK), Abbott Laboratories (Abbott Park, IL), Idec Pharmaceuticals (San Diego, CA), and Abgenix (Fremont, CA) are actively selling their excess capacity. Other sponsors with excess capacity are using their manufacturing capabilities as leverage when negotiating alliances.

After talking to industry insiders, it is clear that the catastrophic supply shortfalls that some observers were forecasting are not coming to pass. According to Howard Levine, president of BioProcess Technology Consultants (Concord, MA), the projections were often faulty assumptions regarding dosage requirements, approval rates, and the market’s ability to absorb all of the new products.

According to Levine and other industry professionals, contract capacity for process development and the biomanufacturing of clinical trial materials is in short supply. The clinical trial materials business can be very volatile—both Lonza and Cambrex Bio Science (East Rutherford, NJ) have suffered significant revenue and earnings shortfalls this year because of clinical project cancellations and delays. However, even in this difficult funding environment for early stage companies, the demand for clinical manufacturing is high.

The high demand is what keeps companies like Cambrex Bio Science investing in the clinical markets. According to its president, Peter van Hoorn, Cambrex Bio Science recently opened a new process development laboratory in Baltimore, Maryland, and is installing a 500-L stirred-tank mammalian-cell culture bioreactor that will begin operation at year’s end. The company is also installing a 2500-L microbial reactor train at its facility in Hopkinton, Massachusetts, which will come on-line in mid-2004.

Small companies adding clinical cell-culture capacity include Laureate Pharma (Princeton,
Outsourcing Outlook

NJ) and Henogen (Charleroi, Belgium). Laureate Pharma recently installed a 200-L bioreactor, and Henogen recently acquired 4C Biotech (Seneffe, Belgium) which provides clinical-scale biomanufacturing.

Baxter expands parenteral operations

One segment of the market that seems assured of having plenty of capacity is contract parenteral manufacturing. Fill-and-finish contractors are in the midst of a $400–500-million investment boom that will substantially increase filling and lyophilization capacity.

Baxter Pharmaceutical Solutions (BPS) (Bloomington, IN) recently announced a massive investment program. BPS will invest $100 million in a 120,000-ft² expansion of its parenteral manufacturing capacity, which will include more filling lines for vials and pre-filled syringes, a new lyophilization unit, and laboratory space. The expansion will nearly double Baxter’s pre-filled syringe capacity to allow for approximately 235 million units annually. The expansion program will be spread throughout seven years, with the new capacity from the initial phase expected to be in operation in 2005.

Aside from the scale of the investment, the BPS announcement is significant because it indicates that BPS clients will have access to parent company Baxter Healthcare’s portfolio of formulation and drug delivery technologies for poorly soluble drugs. This portfolio includes the Nano-edge technologies that Baxter licensed from RTP Pharma in 2001 and the controlled-release protein and pulmonary delivery technologies that Baxter gained when it acquired Epic Therapeutics, Inc., in 2002.

Formulation technology may begin to rival process technology as a competitive factor in the fill-and-finish sector. With so much investment in capacity, companies will try to differentiate themselves along other dimensions.

AAI recommits to service business

AAI Pharma (Wilmington, NC) has renamed its contract services unit from AAI International to AAI Development Services and has undertaken several initiatives to upgrade its contract services offerings. The move is part of an effort to get AAI Pharma’s services business back on track after more than a year of declining revenues and profits. Development services revenues of $82.4 million in 2002 were down 11% from 2001, and first quarter 2003 revenues of $20.2 million were down 13% from the year before.

In its announcement of the name change, the company said it is “undertaking a renewed commitment to getting the job done right and on-time for customers.” In particular, AAI Development Services is realigning its sales and customer service–project management staff to work together in client-focused teams that will give the client a single point of contact, according to Stephen Cottrell, executive vice president for sales and marketing.

The company also announced several investments to upgrade its capabilities. These investments include a $2-million renovation of its solid dosage manufacturing facility in Wilmington, North Carolina, a 50% increase in storage capacity, and the addition of explosion-proof capabilities for handling alcohol-based products at its Charleston, South Carolina, facility.