Second quarter sees 3 firms raise \$56.3 million

NEW YORK—Though it got off to a fast start, this year's first quarter saw public financing of U.S. biotech companies take a tumble. Indeed, in late February, after Synergen (Boulder, CO) reported disappointing results from phase-III clinical trials of its high-profile sepsis product, public financing bottomed out, as the biotech sector lost 33 percent of its market value. In January and February, before the Synergen debacle, 21 companies raised \$550 million. Yet in March, after the Synergen debacle, six companies raised \$99.5 million.

This year's second quarter, for its part, saw public financing grind to a halt, with just three companies taking in a paltry \$56.3 million

(Table 1). The public-financing window slammed shut not only because of product disappointments but also because of uncertainty over the Clinton administration's promised health-care reform. Investors are increasingly concerned that the administration will attack not just the high prices of me-too pharmaceuticals but the sky-high prices of innovative biopharmaceuticals as well.

Without access to public financing, companies turned with a vengeance to private financing during the second quarter, with 17 firms capturing \$149.8 million. April saw five companies take home \$47.2 million, as Hybridon (Worcester, MA) raised \$20 million, Myriad

Genetics (Salt Lake City, UT) netted \$10 million, Ascent Pharmaceuticals (Billerica, MA) took in \$6.2 million, Prizm Pharmaceuticals (San Diego, CA) captured \$6 million, and Arcturus Pharmaceutical (Cambridge, MA) netted \$5 million. May saw four companies raise \$24 million, with Tularik (S. San Francisco, CA) taking home \$17.4 million, DynaGen (Cambridge, MA) capturing \$4 million, Imre (Seattle, WA) netting \$2 million, and Editek (Burlington, NC) taking in \$650,000. And in June, eight companies raised \$78.6 million, as Alpha-Beta Technology (Worcester, MA) captured \$20 million, Onyx Pharmaceuticals (Richmond, CA) netted \$12.2 million, Geron (Menlo Park, CA) brought in \$10.7 million, Celtrix Pharmaceuticals (Santa Clara, CA) raised \$10.5 million, NeoRx (Seattle, WA) took home \$9 million, Alexion Pharmaceuticals (New Haven, CT) captured \$8 million, Canji (San Diego, CA) netted \$5.6 million, and Ophidian Pharmaceuticals (Madison, WI) brought in \$2.6 million.

—B.J. Spalding

TABLE 1.
Biotech's 1993
second-quarter
offerings.

Company	Focus	Date	Money Raised (\$ Millions)	Post-Money Valuation (\$ Millions)
Initial Public Offerings				
Telor Ophthalmic Pharmaceuticals	Ophthalmic therapies	May	23.0	61.6
Secondary Public Offerings				
Cephalon	CNS therapies	April	21.8	104.5
ImClone Systems	Infectious disease	May	11.5	66.1
Totals			56.3	232.2
IPOs in process: Genzyme Transgenics, Innovir Laboratories, Transkaryotic Therapies.				
Secondaries in process: American Biomed, Cygnus Therapeutics, Meridian Diagnostics, Vicat.				
Source: Recombinant Capital (San Francisco, CA).				

Several financial analysts believe that Vestar suffered a severe setback at the FDA advisory committee meeting.

FDA advisory panel nixes Vestar's DaunoXome

WASHINGTON, D.C.—The Oncologic Drugs Advisory Committee of the Food and Drug Administration (FDA, Bethesda, MD) recently recommended against approving Vestar's (San Dimas, CA) DaunoXome—a liposomal formulation of the anticancer drug daunorubicin—for treating AIDS patients with Kaposi's sarcoma (KS), a life-threatening malignancy that affects 15 percent of AIDS patients. Although financial analysts are calling the advisory committee's move a disaster for Vestar, Vestar officials insist that DaunoXome, which was on an extraordinary fast track at FDA, has merely been set back, not derailed. Vestar is currently conducting a phase III trial of DaunoXome for AIDS-related KS.

Vestar submitted its new drug application (NDA) for DaunoXome to FDA in February. The NDA included data from a phase II clinical trial of 39 AIDS patients with KS

who had already failed other forms of KS treatment, including several conventional anticancer drugs as well as alpha interferon. FDA's unusually fast response to DaunoXome's NDA, a bare four months, reflects, in part, "how seriously we're taking our promise to review NDAs for drugs for life-threatening diseases very quickly, within six months," says Adele Seifried, the executive secretary of the Oncologic Drugs Advisory Committee. Revenues from new user fees will soon enable FDA to continue to accelerate such reviews.

A serious drawback to rapid reviews, however, is that they reduce the time available for FDA and company officials to analyze—and potentially resolve—differences of opinion over a candidate product before airing them in public. FDA officials suggest that at least some of the fuss over Vestar's DaunoXome was about form, not substance.

Yet much of the fuss involved substance. "Basically, Vestar included a lot of patients that should not have been counted according to the protocol" for their clinical trial, Seifried says. "When FDA excluded them, the analysis came out significantly different."

For example, Vestar representatives say that their data indicate a 51-percent partial-response rate among patients who were treated with DaunoXome. However, FDA officials say the apparent partial-response rate drops to 18 percent once the protocol's exclusion criteria are applied. Vestar, for instance, counted some patients as responding to DaunoXome before they had maintained that response for a minimal period of four weeks. Moreover, some patients Vestar counted were developing new breakthrough lesions, an indication that they were not responding to DaunoXome. There were also unanswered safety questions, with some data suggest-