



LIFE SCIENCES BULLETIN

Spring 1999
Volume VI, Issue 1

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Published by the Life Sciences Group of
Wilson Sonsini Goodrich & Rosati,
Professional Corporation.

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Venture Capital Funding of Life Sciences Industry Continued to Grow in 1998

J. Casey McGlynn

Chairman, Life Sciences Group

In 1998, venture capitalists set aside their reservations about the near-term prospects for the life sciences industry and pumped more than \$2.7 billion into life science companies, according to recently released figures. Investments overall rose nearly 10 percent over 1997, as all sectors saw increases in funding, with the exception of biotechnology, where funding remained flat compared to 1997.

The venture community was particularly interested in funding start-up and seed-stage companies, while pulling back from 1997's funding levels for more established venture-backed concerns. In 1998, initial and seed funding of life sciences companies rose nearly 63 percent compared to 1997, while funding for late-stage companies fell nearly 46 percent from the prior year's levels.

Many industry observers attribute the slowdown in late-stage funding to the public market's lack of receptivity for healthcare IPOs, compounded by a shift in strategic focus by large healthcare companies that have, in past years, been avid buyers of young, venture-backed companies.

"Conditions in the public markets have compressed valuations. That has made it tougher for later-stage companies to get the step-ups in valuation that they are used to getting," observed Tracy Lefteroff, partner-in-charge of the Global Life Sciences Practice for PricewaterhouseCoopers LLP, which conducted the annual VC survey.

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Venture Capital Continued to Grow...

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Venture Capital Invested in Life Sciences Companies (\$ in millions)

	1998	% Change from 1997	# of 1998 Deals	Avg. 1998 Deal Size
Biotechnology	\$638.5	(1.3%)	140	\$4.6
Healthcare Information & Services	\$1,100.9	6.6%	256	\$4.3
Medical Devices & Diagnostics	\$686.6	11.5%	173	\$4.0
Pharmaceuticals	\$324.7	43.9%	51	\$6.4
TOTALS	\$2,750.7	9.1%	620	\$4.4

Figure 1 source: PricewaterhouseCoopers LLP

Top 10 Venture Capital Deals of 1998 (\$ in millions)

Company Name	Amount Raised	Round	Company Description
PRAECIS Pharmaceuticals Inc. (Cambridge, MA)	\$37.8	Third	Developer of peptide-derived pharmaceuticals
The Medicines Company (Cambridge, MA)	\$36.0	Fourth	Developer of prescription medicinal products
Brandywine Senior Care Inc. (Cherry Hill, PA)	\$32.0	Second	Complete continuum of healthcare for seniors
Dyax Corporation (Cambridge, MA)	\$31.4	Mezzanine	Proprietary technologies to discover and develop therapeutic and diagnostic products
Lexicon Genetics Inc. (The Woodlands, TX)	\$31.0	Mezzanine	Selection of drug targets using functional genomic technology
Ontogeny Inc. (Cambridge, MA)	\$28.0	Fourth	Developmental biology to create therapies to combat disorders associated with loss of cell function
Instrumentation Metrics Inc. (Tempe, AZ)	\$23.7	Second	Non-invasive clinical and industrial diagnostic instrumentation
Protocare Inc. (Santa Monica, CA)	\$23.5	First	Health services consulting and clinical trial management
Aspen Youth Services (Cerritos, CA)	\$22.5	First	Education and treatment services for at-risk youth
Cell Pathways Inc. (Horsham, PA)	\$21.6	Fourth	Pharmaceutical compounds to induce apoptosis in neo-plastic tissue

Figure 2 source: PricewaterhouseCoopers LLP

Not all late-stage companies found it tough going, however. The top recipient of venture capital funding in the life sciences in 1998 was PRAECIS Pharmaceuticals, a Cambridge-based developer of peptide-derived pharmaceuticals. The company raised \$37.8 million in third-round funding during the second quarter. Lexicon Genetics, a functional genomics company based in The Woodlands, Texas, received the most money among biotechnology concerns, raising \$31 million in mezzanine round funding during the second quarter.

Instrumentation Metrics, which is developing non-invasive clinical and industrial diagnostic instrumentation, raised the most funding among medical device and diagnostic companies, with a \$23.7 million second round in the first quarter. Brandywine Senior Care, which is creating a continuum of healthcare services for seniors, garnered the most funding among healthcare information and services companies, raising \$32 million in second round funding during the first quarter.

Top Recipients of Seed or First-Round Venture Capital

We pay particular attention to the companies receiving seed and first-round venture capital funding, because we believe

that these investments signal the birth of a significant new, fast-growing new business that in future years will likely go public, merge or be acquired by another entity.

Among companies receiving seed or first-round funding, the recipient receiving the most funding was a healthcare services concern, Protocare, Inc. of Santa Monica, which received \$23.5 million for its health services consulting and clinical trial management business. The top seed or first-round recipient in the medical device and diagnostics sector was Stereotaxis, Inc. a St. Louis-based company that raised \$18 million in first-round funding to develop a magnetic stereotaxic system, which is a new concept for the delivery of therapeutic agents.

The top seed or first-round recipient among biotechnology companies was Esperion Therapeutics of Ann Arbor, which raised \$15 million to help it develop therapies for atherosclerosis and cardiovascular diseases. Novirio Pharmaceuticals of Cambridge raised \$11 million to develop oral anti-viral therapeutics, making it the recipient of the largest seed or first-round funding in the pharmaceutical sector.

For a complete listing of the top recipients of venture capital funding in each life sciences industry sector, please visit the Life Sciences Bulletin section of the WSGR web site at <http://www.wsgr.com>.

Top 10 Seed or First-Round Financings

Company	Amount (in millions)	Quarter	Description
Protocare Inc. (Santa Monica, CA)	\$23.5	First	Health services consulting and clinical trial management
Aspen Youth Services (Cerritos, CA)	\$22.5	Fourth	Education and treatment services for at-risk youth
Women's First Healthcare (Rutherford, NJ)	\$21.0	First	Development, marketing and distribution of pharmaceuticals and (E. nutraceuticals for women
Stereotaxis Inc. (St. Louis, MO)	\$18.0	Third	Developer of magnetic stereotaxis system for delivery of therapeutic agents
Esperion Therapeutics Inc. (Ann Arbor, MI)	\$15.0	Third	Developer of therapies for atherosclerosis and cardiovascular diseases
AGY Therapeutics Inc. (San Mateo, CA)	\$13.75	Second	Developer of pharmaceuticals related to neurobiology
Radiant Medical (Portola Valley, CA)	\$12.5	Fourth	Devices for neurovascular disorders
Iconix Pharmaceuticals (Mountain View, CA)	\$12.5	Third	Genomics-based assay platform to enable validation of new drug targets and identification of chemical leads in parallel
Novacept (Palo Alto, CA)	\$12.0	Third	Endometrial ablation device systems
Novirio Pharmaceuticals Inc. (Cambridge, MA)	\$11.0	Second	Oral antiviral therapeutics

Figure 3 source: PricewaterhouseCoopers LLP

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Venture Capital Continued to Grow...

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Funding by Rounds, 1997-98 (\$ Amounts in Millions)

	1998	1997	% Change 1997 to 1998
Start-up/Seed	\$366.0	\$225.0	62.7
Early	\$773.8	\$727.9	6.3
Expansion	\$820.0	\$822.7	(0.3)
Late	\$206.6	\$379.8	(45.6)

Figure 4 source: PricewaterhouseCoopers LLP

Initial Public Offerings in 1998

Company	Date of Offering	Amount Raised (in millions)	Description
BMJ Medical Management (Boca Raton, FL)	February 4	\$28.0	Provider of management services to physician practices focusing on musculoskeletal care
Province Healthcare Co. (Brentwood, TN)	February 11	\$75.2	Operator of non-urban hospitals
Balanced Care (Mechanicsburg, PA)	February 12	\$45.5	Developer of senior-care continuums in secondary markets
Symphonix Devices (San Jose, CA)	February 13	\$27.6	Developer of semi-implantable and implantable hearing devices
LJL Biosystems (Sunnyvale, CA)	March 13	\$14	Developer and marketer of proprietary technologies and products to accelerate and enhance the drug discovery process.
Nanogen (San Diego, CA)	April 14	\$42.9	Commercializer of gene discoveries for not-for-profit research institutions
American Dental Partners (Wakefield, MA)	April 15	\$33.75	Operator of dental facilities
Iomed (Salt Lake City, UT)	April 24	\$12.75	Developer of iontophoresis drug-delivery systems
Combichem (San Diego, CA)	May 8	\$18	Provider of combinatorial-chemistry services
Ribogene (Hayward, CA)	May 28	\$16.1	Developer of antibacterial therapeutics using translational control as a mechanism for developing drugs to fight cancer
V I Technologies (Melville, NY)	June 11	\$36	Developer of blood-related products and technology
Abgenix (Fremont, CA)	July 2	\$20	Developer of antibody therapeutic products for the prevention and treatment of a variety of diseases
Eclipsys (Delray Beach, FL)	August 7	\$63	Developer of healthcare software
New American Healthcare (Brentwood, TN)	August 20	\$65	Owner and operator of acute-care hospitals

Figure 7 source: VentureOne

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Difficult Year for IPOs

The 1998 market for life sciences IPOs was the worst in years. Only 14 companies successfully completed initial public offerings in 1998, down from 41 in 1997. The 1998 IPO window for healthcare companies slammed shut during last summer's stock market declines and by year-end had not reopened.

The last life sciences IPO of the year was done on August 20 by New American Healthcare, an owner-operator of acute-care hospitals. The largest life sciences IPO of 1998 was Province Healthcare Co.'s \$75.2 million offering on February 11, 1998. Province, based in Brentwood, Tenn., operates hospitals in non-urban areas.

Total number of IPOs, 1995-98

Year	Number of IPOs	Amount Raised (in millions)
1995	49	\$1,634
1996	81	\$2,758
1997	41	\$1,226
1998	14	\$497.8

Figure 8 source: VentureOne

Geographic Distribution of Venture Capital Financings (\$ in millions)

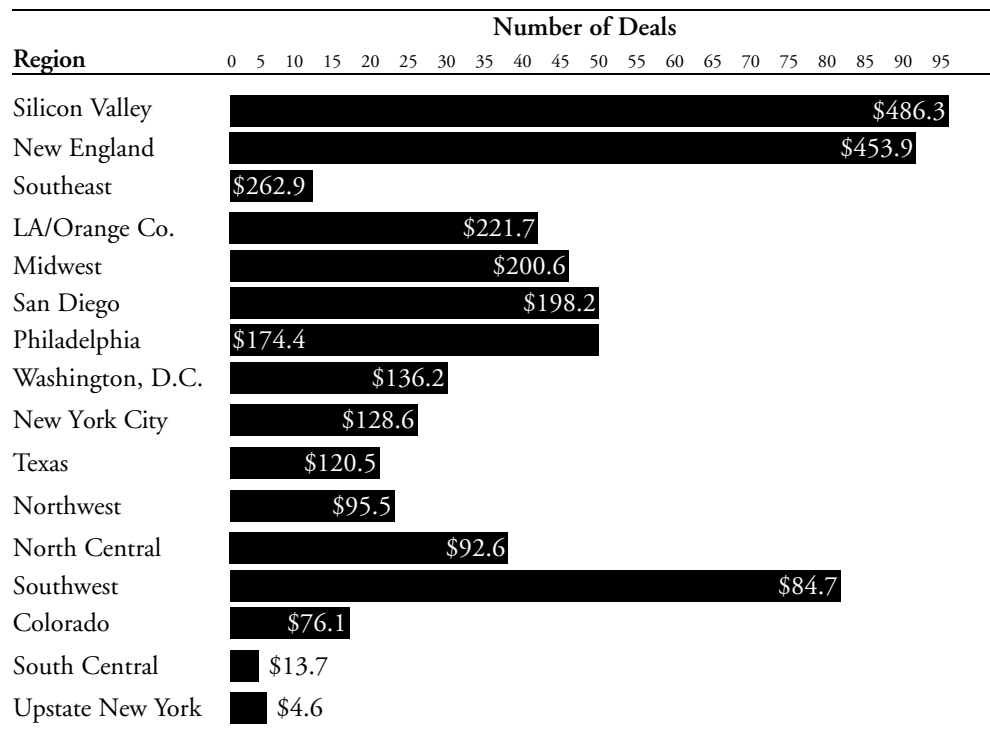


Figure 5 source: PricewaterhouseCoopers LLP

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Venture Capital Continued to Grow...

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VC Investment Trends

During 1998, the sector experienced the further “nationalization” of the market for healthcare venture capital investment dollars. While Northern California continued to collect the most venture capital money as a region, Northern California companies did none of the year’s top 10 deals. Northern California continues to be a hotbed of entrepreneurial activity, however, as four of the top 10 first-time financings of life sciences companies occurred there.

Another interesting trend in life sciences funding is the growing specialization of venture capital firms. VC firms interested in funding the life sciences are increasingly forming special pools that invest exclusively in this sector. During 1998, one such fund, MedVentures Associates II, was the fourth most-active funder, participating in 14 deals. However, the top dealmaker of the year was a diversified fund, the Sprout Group, which participated in 24 life sciences deals.

1999 Outlook

Despite the uncertainty that marked 1998, some trends emerged that should continue into 1999. For the foreseeable future, funders are likely to continue to fund early stage and start-up ventures, as they wait for the public market to regain its appetite for late-stage companies trying to go public.

1998 Top Life Sciences Funders

Firm	Number of Deals
Sprout Group	24
New Enterprise Associates	22
Alta Partners/Burr Egan Deleage & Co.	18
MedVentures Associates II	14
Boston University Community Technology Fund	13
S.R. One Ltd	12
Pacific Venture Group	12
Mayfield Fund	10
Child Health Investment Corp.	9
Ben Franklin Technology Center of SE Penn.	8
BancBoston Capital	8

Figure 6 source: PricewaterhouseCoopers LLP

In the near-term, some industry observers believe that biotech ventures may have a tough time securing funding. Investors appear to be concerned about the long time-to-market for companies engaged in initial research and development efforts, favoring instead companies that already have products in later stages of development.

Still, the long-term prospects for the industry remain bright. “We remain solidly convinced that venture capital funding of life sciences start-ups is an excellent business to be in, even as the marketplace sorts out issues surrounding valuation and business models,” said A. Grant Heidrich, a general partner of Mayfield Fund. “Companies continue to bring us exciting new ideas that are literally the future of healthcare,” Heidrich added.

PricewaterhouseCoopers’ Lefteroff added: “The demographics for healthcare, including an aging population worldwide, means we are going to see continued or increased investment in the emerging healthcare sector for some time to come.”

We feel confident that long-term trends favor development-stage companies. These companies have taken the lead in creating the products and technologies that will fill the pipeline for new healthcare products and services for years to come. ❖

Visit our website for a complete listing
of VC funding by sector.

www.wsgr.com

Note on Sources: The data in figures 1-6 on venture capital funding of the life sciences was compiled from the PricewaterhouseCoopers Money Tree™ Survey. Historical venture capital data provided here may differ from the 1997 Life Sciences Bulletin report due to a change in sources for venture capital data. VentureOne provided the IPO data in figures 7 and 8.

PricewaterhouseCoopers Money Tree Survey Methodology: PricewaterhouseCoopers sends out quarterly survey forms to venture capital firms, which must be returned by the 15th of the month after the close of the quarter for data to be included in the survey. PricewaterhouseCoopers verifies submissions by contacting selected companies and by comparing information provided against secondary sources. While we feel confident that PricewaterhouseCoopers has provided us with a view of venture investing in the life sciences, neither PricewaterhouseCoopers LLP nor Wilson Sonsini Goodrich and Rosati make any claim or warranty about the overall accuracy of the data.

For further information: For more data on venture capital funding of the life sciences, visit the Life Sciences Bulletin page on the WSGR web site at <http://www.wsgr.com>. For more information about venture capital funding in general, visit PricewaterhouseCoopers’ Money Tree web site at <http://www.pwcmoneytree.com>.

FDA Financial Disclosure Regulations Go into Effect

David M. Hoffmeister
Drug and Device Regulatory Law Practice

On February 2, 1999, new Food and Drug Administration (FDA) regulations went into effect that require companies seeking FDA marketing approval disclose whether they have provided significant compensation, financial support or incentives to investigators who participated in key clinical trials.

The FDA (the "Agency") implemented this rule "to make the Agency aware of payments and financial arrangements ... that could lead to bias in the clinical trial process, so that this can be taken into account in the review process."

Only those trials "that the applicant or the FDA relies on to establish that the product is effective (including studies that show equivalence to an effective product) or any study in which a single investigator makes a significant contribution to the demonstration of safety" are covered under this regulation. The Agency excluded from "large open safety studies conducted at multiple sites," as well as Phase 1 tolerance or pharmacokinetic studies, most clinical pharmacology studies, treatment protocols and parallel track studies.

All New Drug Applications (NDAs), Product License Applications (PLAs) for biologics and Premarket Approvals (PMAs) for medical devices filed after February 2, 1999 were likely to be affected by this new regulation. The Agency forecasted that only 5 percent of the estimated 6,000 annual 510(k) medical device applications would include the financial disclosure requirement.

The FDA is not requiring that all financial arrangements between trial sponsors and clinical investigators be disclosed. Instead, it established thresholds that would necessitate disclosure. Below the threshold, applicants only have to file a certificate stating that the financial arrangements, if any, between the trial sponsor and the investigators did not exceed the threshold amounts. Due to these thresholds, the Agency estimated that no more than 10 percent of applicants would have to file disclosure forms.

The date the regulation went into effect, February 2, is a key date which determines the type of disclosure required, depending on the type of financial arrangement and whether the applicant is a publicly traded company. Please see the "Key Provisions" section below for details.

Brief History of the Legislation

In June 1991, the Inspector General of the Department of Health and Human Services submitted a management advisory report to the FDA saying that the Agency's failure to have a mechanism for collecting information on potential financial conflicts of interest among clinical investigators could constitute a "material weakness" under the Federal Managers' Financial Integrity Act. The FDA disagreed with the "material weakness" assertion, but nevertheless initiated the rulemaking process with regard to financial disclosure.

Following meetings with industry representatives, scientific and healthcare organizations and consumer groups, as well as a hearing of its Science Board in September 1993, the FDA formally proposed a financial disclosure rule on September 22, 1994. A 90-day comment period ensued, during which the Agency received 58 comments, many harshly critical of the need for this level of scrutiny and suggesting that it would cause an undue data-collection burden on industry. In response to the criticism, the FDA held a public hearing on July 20, 1995 and then convened a second meeting of its Science Board on March 29, 1996.

The final rule was many months in development and was not ultimately published until February 2, 1998. The Pharmaceutical Research and Manufacturer's Association (PhRMA) filed a Petition for Reconsideration, citing several perceived flaws in the final rule, including vagueness in the definition of "covered clinical study" and the rule's requirement for retrospective collection of data. The petition was granted in part, resulting in a tightening of the language regarding covered clinical studies and the retrospective collection of data. As stated above, the regulation formally went into effect on February 2, one year after publication of the final rule.

Key Provisions

This regulation covers clinical trials that establish effectiveness or make a significant contribution to the demonstration of product safety. Certain types of trials, as listed above, may be excluded. Applicants are encouraged to consult with the Agency if they are unclear about whether a trial is subject to this provision.

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FDA Financial Disclosure...

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The regulation requires that a financial disclosure filing be made regarding any clinical investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. Disclosure must be made not only about the investigator's financial relationship with the trial sponsor, but also any financial relationships between the sponsor and an investigator's spouse or dependent child.

Investigators are required to cooperate with trial sponsors and provide the data, but ultimately, it is the applicant's responsibility to file correct information about each investigator in a covered trial. (The Agency did include a loophole allowing the sponsor claim that after acting with "due diligence" to gather the data, they were unable to).

For each investigator involved in a clinical trial, the applicant must report either:

- that they are full- or part-time employees of the applicant (who are exempt from this regulation);
- that no financial arrangements exist that exceed the Agency's thresholds; or
- the nature of financial arrangements between the applicant and the investigator.

The Agency did not commit to keeping all information disclosed under this regulation confidential, saying "there may be legitimate public interest in the information that warrants disclosure." However, the Agency pledged to keep confidential certain types of information, such as equity interests, "unless circumstances clearly outweigh the privacy interest."

The FDA defined the types of financial information that would trigger disclosure as follows:

- Any compensation that would be affected by the outcome of clinical studies, such as compensation that is explicitly greater for a favorable result or compensation tied to sales of the product, such as a royalty;
- An equity interest in the sponsor of a covered study that exceeds \$50,000 during the time of the investigator is carrying out the study and for a period of one year following completion of the study;
- Significant payments of more than \$25,000 made by the sponsor to the investigator or the investigator's institution, excluding the costs of conducting the clinical trial or other clinical studies, during the study period or for one year following completion.

If none of these thresholds is met, the applicant only has to submit a certificate stating this fact.

In response to PhRMA's petition, the FDA clarified the timeframes related to each type of financial arrangement. For investigators with stock in a publicly held company, applicants are required to collect information regarding those interests only for studies that were ongoing on February 2, 1999. For those with stock in private companies, or for those receiving compensation affected by the trial outcome, the requirement is triggered if the application is made after February 2, 1999, regardless of when the trial took place. Under the "significant other payments" category, only such payments made on or after February 2, 1999 must be reported.

How the FDA Will Use This Information

In the preamble to the final rule, the FDA said it planned to use this information "in conjunction with information about the design and purpose of the trial, as well as information obtained through on-site inspections, to assess the reliability of the data."

In its analysis, the Agency said it would take into consideration "the size and nature of a disclosed financial interest" as well as steps taken to "minimize the potential for bias." When it factors in study design, the Agency said that approaches such as multiple investigators, blinding, objective endpoints or measurement of objective endpoints by someone other than the investigator "may adequately protect against any bias created by a disclosable financial interest."

If the FDA determines that a financial interest raises serious questions about the integrity of the data, the Agency will take "any action it deems necessary to ensure the reliability of the data," including the initiation of an audit; requesting further analyses of the data; requesting additional studies to confirm the questioned study; or refusing to treat the covered clinical study as providing usable data.

Trial sponsors were urged to confer with the FDA prior to initiation of a study if potential questions about the reliability of the data might later arise as the result of the financial disclosure requirement.

Failure to file either a certificate or the requisite financial disclosure forms may result in the FDA refusing to file a marketing application.

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Steps to Ensure Compliance with This Regulation

In the preamble to the final rule, the FDA said it planned to WSGR recommends that trial sponsors and marketing applicants update their clinical procedures to comply with this new provision. Timely compliance measures will minimize administrative burdens and reduce the possibility that a trial will be tainted, or a marketing application delayed, by questions about financial arrangements with investigators. Trial sponsors should immediately revise their standard contracts to reflect the need for financial disclosure, while making a thorough survey of relationships with existing investigators. New tracking systems may be needed to monitor equity interests, patents and/or royalty interests of investigators, as well as grants made to an investigator or their institution. In its final rule, the FDA said that applicants must maintain these records for two years after product approval. ♦

FDA VIDEO CONFERENCE SERIES

THE NEW QUALITY SYSTEM INSPECTION TECHNIQUES

May 5, 1999

San Mateo Marriott
San Mateo, California

9:00 a.m. — 2:00 p.m.

This video satellite program will explore the new inspection process that will replace the current medical device quality system inspection process. You will have the additional opportunity to hear the perspective of Ron Johnson, former Regional Director of FDA's San Francisco Field Office, and now Executive Vice President at Quintiles Consulting, and John Arnold, a field inspector with FDA for more than 30 years and now an industry consultant. David Hoffmeister, Head of WSGR's Drug & Device Regulatory Group, will lead the lunch discussion. For more information, call 650-858-4443.

Biopharmaceutical Executives Assess Future Prospects

While acknowledging that this is a difficult time for the biopharmaceutical sector, industry executives attending the "Financing the Biopharmaceutical Company" conference in February agreed that the long-term prospects for the industry remain strong.

"I believe that the struggles being experienced by some in the industry are the natural result of the creative process. The industry will come out of this period stronger and better positioned to develop and commercialize the health care breakthroughs of tomorrow," said A. Grant Heidrich, a general partner of Mayfield Fund.

Mayfield Fund co-sponsored the conference along with the Life Sciences Group of Wilson Sonsini Goodrich & Rosati. The conference, held in Redwood Shores, Calif., drew 300 participants, including senior executives of biopharmaceutical companies, as well as venture capitalists, attorneys and consultants to the industry.

Edward E. Penhoet, Ph.D., director and co-founder of Chiron Corporation, opened the conference as keynote speaker. Penhoet told the audience that the industry has largely delivered on its initial promise, which was to identify prime targets for genetic engineering and prove that they could be commercialized. Penhoet added, "The future for biopharmaceuticals is very positive. Consumers are going to be more of a factor in driving their health care, because of the information they download from the Internet."

Among the conference topics were sessions exploring industry consolidation, trends in mergers and acquisitions, creative financing techniques and the structure of cross-border deals.

In addition to Penhoet, McGlynn and Heidrich, conference speakers included G. Steven Burrill of Burrill & Co., Kenneth Clark of WSGR, Jon Duane of McKinsey & Co., Patrick Enright of Diaz & Altschul, Frederick Frank of Lehman Brothers, Russell Hirsch of Mayfield Fund, Steve Holtzman of Millennium Pharmaceuticals, Vaughn Kailian of COR Therapeutics, Inc., Roger Longman of Windhover Information, Benjamin McGraw of Megabios Corp., Michael O'Donnell of WSGR, Stelios Papadopoulos of PaineWebber, George Scangos of Exelixis Pharmaceuticals, Stephen Sherwin of Cell Genesys, and John Walker of Axys Pharmaceuticals, Inc. ♦

FDA Alert

David Hoffmeister and Jon Nygaard

Status Update - Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics and Devices.

In July 1998, U.S. District Court Judge Royce Lambreth issued a ruling in a case brought by the Washington Legal Foundation ordering the FDA not to limit pharmaceutical or medical device manufacturers from:

- disseminating to medical professionals articles published in peer-reviewed journals that discuss off-label uses of drugs or devices;
- disseminating to medical professionals textbooks, or portions of them, published by bona fide publishers that discuss off-label uses;
- suggesting content or speakers to an independent provider of continuing medical education programs at which off-label uses were to be discussed.

The case had come before him when WLF challenged three guidance documents issued by FDA in which manufacturers were limited in these activities. Judge Lambreth found those limitations violative of the First Amendment by unduly restricting companies from communicating truthful information about their products.

At the time of this ruling the Food and Drug Administration Modernization Act of 1997 ("FDAMA") had been enacted but the rule implementing its provisions vis-a-vis dissemination of information on off-label uses had not been issued. Although Judge Lambreth referenced FDAMA in his order, he did not specifically state that his injunction applied to the new law.

In November 1998, the FDA issued a final rule pertaining to off-label uses. It closely tracked Section 401 of FDAMA, which is very detailed and permits manufacturers to disseminate information regarding new or off-label uses provided they comply with certain statutory requirements. For example, both FDAMA and the final rule require companies to (1) submit a supplemental marketing application for the new use within a certain period of time; (2) submit the materials to the FDA 60 days in advance of dissemination; and (3) include with the materials a statement that the use in question is not approved. The regulations include many other requirements as well.

In February 1999, Judge Lambreth clarified his decision that his injunction applies only to unapproved uses of drugs

or devices previously approved by the FDA for some other use, not to products that have not received approval for any use. More importantly, he refused to restrict the scope of his earlier order to the three guidance documents. Rather, he found that FDA's policies imposed an unconstitutional burden upon First Amendment rights. He did not address whether FDAMA perpetuates these policies but requested both parties to brief the issue. FDA filed its brief at the end of March; WLF will be filing its response in April. A decision from Judge Lambreth will issue sometime thereafter.

It is very possible that Judge Lambreth will determine the FDAMA and its implementing regulations are in violation of the First Amendment. If so, manufacturers will be free to disseminate peer-review journal articles containing off-label information about approved drugs or devices without having to comply with the new FDAMA regulations. We will keep you advised. In the meantime, we would be happy to discuss and explore with you what information you might legally disseminate to medical professionals. Call us at (650) 493-9300 or reach us via e-mail at dhoffmeister@wsgr.com and jnygaard@wsgr.com. ❖

Life Sciences Events

This is a sampling of the transactions recently completed by the Wilson Sonsini Goodrich & Rosati Life Sciences clients (indicated in bold) during the first quarter of 1999.

Public Offerings

WSGR assisted life sciences companies in raising over **\$150 million** in the following public offerings.

Anesta Corporation, developer of pharmaceutical oral transmucosal products, completed a common stock offering for \$64 million. Underwriters included BancBoston Roberston Stephens and Volpe Brown Whelan & Company.

Healtheon Corporation, provider of an internet-based platform for the healthcare industry, completed an initial public offering for \$40 million. Morgan Stanley Dean Witter, Goldman Sachs & Co., Hambrecht & Quist, and Volpe Brown Whelan & Company served as underwriters.

Abgenix, Inc., provider of antibody therapeutic products, completed an offering of common stock for \$45 million. Underwriters were BancBoston Roberston Stephens, Lehman Brothers and Pacific Growth Equities, Inc.

Corporate Partnerships/Joint Ventures

Kosan Biosciences, Inc. entered into a research and licensing agreement with RW Johnson Pharmaceutical Research Institute and Ortho McNeil Pharmaceutical, Inc. Kosan and the Johnson & Johnson companies will collaborate to discover and develop products for the treatment of bacterial infections.

Venture Investments

December 31, 1998 and March 31, 1999, WSGR assisted its life sciences clients in raising over \$100 million from venture investments. Venture financings were completed for a number of WSGR clients including: **A-Med Systems, Inc.**, **BioCardia, Inc.**, **Cardiovasc**, **Corazon Technologies**, **EndoVasix, Inc.**, **Neoforma, Inc.**, **Pangea Systems, Inc.**, **Percusurge, Inc.**, **PraxSys BioSystems, Inc.**, **VNUS**.

WSGR Seminars

MARK YOUR CALENDARS!

■ Allicense 99

Co-Sponsored by WSGR and Recombinant Capital
April 27-28, 1999
Ritz Carlton, San Francisco

For information, call 415-433-1720 or visit www.recap.com

■ FDA Satellite Video Conference Series

The Drug and Device Regulatory Law Practice at WSGR will sponsor the next FDA Satellite Video Conference:

- *The New Quality System Inspection Techniques*
This seminar will be held on Wednesday, May 5, 1999 at the San Mateo Marriott in San Mateo, California from 9:00 a.m. to 2:00 p.m. To register, please call 650-858-4443.

■ The Seventh Annual Medical Device Conference

June 10, 1999, 8:30 a.m. - 5:30 p.m.
The Fairmont Hotel, San Jose, California

For information, call 650-858-4428 or visit www.usgr.com

■ The Sixth Annual Euro-Biotech Forum

June 13-15, 1999
Majestic Hotel, Cannes, France

For information call 203-838-4401 ext. 101 or visit www.windhoverinfo.com

■ Future FDA Satellite Video Conferences

Mark your calendars:

- *July 21, 1999*
- *November 10, 1999*

**Please Join Us
for
ALLICENSE 99**

*Co-sponsored by WSGR and
Recombinant Capital*

**San Francisco Ritz Carlton
April 27-28, 1999**

**Info: www.recap.com
or call 415-433-1720**

SPEAKERS INCLUDE

Dr. Maria C. Freire
Steve Holtzman
Louis J. Lavigne, Jr.
Arlene M. Morris
Carol Olson
Dr. Julie A. Olson
Dr. Ronald A. Pepin
Howie Rosen
Nicholas J. Simon III
Dr. Wendell Wierenga

Congratulations to

1999 ALLICENSE AWARDS Nominees:

Bayer Corporation and Millennium Pharmaceuticals, Inc.
Eli Lilly and Company and ICOS Corporation
Eli Lilly and Company and Ligand Pharmaceuticals, Inc.
SmithKline Beecham and Coulter Pharmaceutical
Wyeth Lederle Vaccines and Aviron

**Phoenix 99:
The Medical Device and Diagnostics Conference
for Chief Executive Officers**



PHOENIX 99

BY INVITATION ONLY

The Phoenician Resort, Scottsdale, Arizona
October 28-30, 1999

*For further information regarding
Life Sciences Conferences,
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