SOMETHING VENTURED

Venture Capitalists Hop On 'New-Age' Drug Bandwagon

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NEW YORK -- Plant-derived drugs, derisively thought of as "New Age," are anything but new. But only now are these often ancient, botanical medicines grabbing the attention of some 21st century venture capitalists.

A few venture-capital firms are funding companies that have embraced the medical lessons of traditional China and ancient India and are developing medicines from their herbal combinations.

"When you invest in drug companies, it is a binary investment risk: Either you get a winning compound or you get nothing," said Gary H. Stroy, a general partner at Walden International in San Francisco.

But herbal medicines "already come with a history -- sometimes even a 1,000-year history -- of efficacy. They lower the risk of finding leads," especially when used with analytical tools that screen quickly for activity against disease targets, he said.

Contrast that experience with traditional drug discovery and development, where researchers indiscriminately pore over chemical libraries or try to engineer a protein. By the time these drug makers bring a therapy to the market -- if they're even lucky enough to get that far -- 12 to 15 years have elapsed since initial funding, often outlasting the life of the venture partnership, said Robin Bellas, a partner at the Menlo Park, Calif., venture firm Morgenthaler. But if a drug maker starts out with a validated drug lead, this development time can be cut in half, Bellas said.

Because of their centuries of use, botanicals can catapult drug discoverers and developers much closer to creating a safe and effective medicine in less time and money than their chemical and biologic counterparts because these researchers have many relevant and viable leads for new drugs at arm's reach.

Chinese Herbal Trove

PhytoCeutica Inc. (www.phytoceutica.com), founded in September 1998 with $18.5 million in financing, is testing two herbal compounds in early-stage clinical trials: one for severe diarrhea associated with chemotherapies for colorectal cancer, and one for neurological damage associated with acute intracerebral hemorrhagic stroke. The management of the 13-employee start-up believes it can fill the pipeline with additional compounds gleaned traditional Chinese medicine yet validated by Western scientific techniques.

So far, PhytoCeutica, New Haven, Conn., is picking the low-hanging fruit from the 3 plus references to Chinese herbal medicine in published reports and studies as potent candidates.

In the longer term, the compounds will be computer-driven, said Chief Executive Pat Kung, referring to the four-herb design of any Chinese herbal medicine formula. Wit than 500 commonly used herbs, the possible combinations number about 62 billion, said.

"Based on this scheme of the last 2,000 years, we have only scratched the surface of treasure," said Mr. Kung.

To date, there have been few U.S. players investing in this area, but not because the drug industry lacks financial potential. If biotechnology, which has created a market capitalization of more than $350 billion during the past 20 years, can be a guide, the drug industry offers the same chances for wealth creation, analysts said.

Rather, the hesitancy has stemmed from a lack of public acceptance of the products t with many people in the West wary that botanical drugs are the equivalent of "snake

FDA to Set Standards

That could change as the Food and Drug Administration builds the wherewithal to ap botanical drugs. This regulatory imprimatur is vital to the industry's growth. Without validation, the public is apt to steer clear of what's been sometimes derided as "voodo medicine."

With FDA approval, however, analysts believe the public won't care whether the me came from plants, chemicals or proteins -- as long as they safely and effectively treat

Under the current regulatory framework, a company can't secure FDA approval of he pharmaceuticals that physicians will prescribe and health-care insurers will cover. Th changing.

The FDA is designing a pathway for botanical-based medicines that would create ch manufacturing and quality-control standards; establish the information needed to sup clinical trials and mark out clinical development milestones identical to its chemical biologic drug-counterparts.

Observers expect the codification of the agency's most recent draft guidelines, which published in August 2000, sometime this year.

Before the FDA sought to create these regulations, developing approved herbal pharmaceuticals was impossible, said Ancile Pharmaceutical Inc. Chief Executive Ja Thompson. The agency required drug makers to establish the safety and efficacy of e ingredient in combination cocktails and their fixed ratio. The FDA has waived this ru Toxicology studies are still needed, but researchers can conduct them at the same tim human testing.

Ancile (www.ancil.com) has benefited from these changes. Without having to condu additional safety work, the four-year-old San Diego company has brought into the cl compounds improved from combinations of botanical extracts. Ancile's most advanc medicine, a sleep disorder treatment, has completed two Phase II studies and is expe late-stage efficacy trials.

The company plans to begin Phase II studies on its second compound, an anxiety dis treatment, early this year. It also is readying testing on a third compound, a cardiovas therapy, as well as a compound for gastrointestinal disorders. None of this would be such an accelerated period if it weren't for the regulatory shift, Ms. Thompson said.

"The risk of failing is drastically reduced," Thompson said. "But if a drug is going to fail fast. At least with botanical drugs you have invested less time and money when c with the tens of millions of dollars invested before [the chemical or biologic] gets int humans."

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