

business

Businesses rely on phase value

Drug companies testing their promising products realize the significance of reaching Phase 3 - the cusp of success. But failure there can deal a big blow.

By Kimberly S. Johnson and Zach Fox Denver Post Staff Writers

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Bryce Keen, laboratory director for Arca Discovery, prepares solutions at the University of Colorado Health Sciences Center at Fitzsimons in Aurora. The solutions will help measure a compound in blood plasma, two vials of which he holds in the next photo. (Post / Glenn Asakawa)

revealed that Efaproxyn extended survival rates in women who had developed brain cancer as a result of having breast cancer only by one month.

"In our quest to address some of the more pressing health concerns, we don't always have success," said Allos spokeswoman Jennifer Neiman.

Westminster-based Allos was one of at least three metro-area biopharmaceutical companies working on Phase 3 trials, which test a drug's effectiveness in the condition it aims to treat and measure the



Bryce Keen, laboratory director for Arca Discovery, holds two vials with samples of blood plasma at the University of Colorado Health Sciences Center at Fitzsimons in Aurora. (Post / Glenn Asakawa)

After years of work on a promising cancer drug, Allos Therapeutics learned last week that the drug didn't extend survival rates as much as it hoped and canceled its development.

A final clinical study, known as Phase 3 testing,

drug's overall safety in patients.

The two other companies are Denver-based Arca Discovery and Boulder-based Pharmion Corp. Arca is testing a drug, bucindolol, designed to fight advanced heart failure. Pharmion, which specializes in oncology drugs, has three candidates in final-phase testing.

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The trials are a pivotal point for biotechnology companies. Positive trial results and Food and Drug Administration approval are the pinnacle of many years of research and development and millions of dollars in operating costs.

Success not only can send a company's stock soaring, it can make the firm an attractive takeover target for larger biotech and pharmaceutical companies looking to grow their product lines and revenue stream.

The opposite can hold true for failure.

"An active appetite"

"There's an active appetite by big pharmaceutical companies to gobble up late-stage entities," said Adam Rubenstein, assistant director of Fitzsimons BioBusiness Partners Inc., an organization that helps develop early-stage life-sciences companies in the state. "No longer do people feel comfortable paying for (pre-clinical) or Phase 1 companies. They want things closer to commercialization."

A prime example is last year's acquisition of Westminster-based Myogen by Gilead Sciences Inc. for \$2.5 billion in cash. Myogen's pulmonary hypertension drug, ambrisentan, was in Phase 3 trials at the time.

"Gilead didn't have any exposure in cardiology at the time," said Rubenstein, who also runs a blog about the state's life-sciences sector. "If the drug gets approval, they've got a \$500 million- to \$1 billion-a-

year drug. That's another reason big pharma is shopping."

Pharmion Corp., on the other hand, is shopping as well, but with a different focus. The company looks to license oncology-drug candidates that have shown effectiveness but have sat on the back shelf at other companies.

One of its leading candidates, Vidaza, was invented in 1964 and got bounced around to several companies, including Johnson & Johnson, before being licensed by Pharmion in 2001. It was approved for sale in the U.S. in 2004. Vidaza, designed to treat leukemia and anemia, is in final- testing stages for approval in Europe.

Pharmion's chief executive, Patrick Mahaffy, said licensing potential drugs gets Pharmion closer to commercialization faster than the traditional drug-development process, which can take up to 12 years. That process includes years of "discovery" as scientists work on finding a solution that fights a particular ailment.

Two other drugs in Phase 3

Publicly traded Pharmion has two other drugs in Phase 3 trials: Satraplatin is an oral compound used to treat patients with prostate cancer; Thalidomide Pharmion is a hard-capsule drug that treats cancer of plasma cells and skin disease.

Pharmion has a market capitalization of \$970 million and employs 450 worldwide.

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"We tried to land on a business model that wasn't just about chasing the science," said Mahaffy. "It's allowed us to build a focus and compete. ... Now we have a chance to build a sustainable enterprise. If things go right we'll be able to launch a new drug every year."

Michael Bristow founded Arca Discovery several years after starting and developing Myogen.

Bristow said that privately held Arca plans to commercialize bucindolol in the U.S., adding that it's a bad strategy for a biotech to try to position itself to be an acquisition target.

"You gain maximum value by being a real company and moving along at maximum efficiency," he said. "And the various offers you may or may not get might not be adequate, so you need to build the company out."

Allos had planned to field its own sales and marketing organization if Efaproxyn had found success, said Neiman. Right now, the company has 65 employees, but it had hoped to be able to expand.

Losing a drug in the Phase 3 trials is "very common," Neiman said.

But with \$2 million spent in 2006 alone on production of the failed drug, Allos lost time and resources in the final phase of clinical trials.

Allos' next drug, PDX, which attacks a blood cancer called peripheral T-cell lymphoma, is in a Phase 2 trial but could jump the final

phase because it addresses an unmet medical need, Neiman said.

Allos stronger, analyst says

The company's stock held steady through Thursday but took a 14 percent dive Friday, down 75 cents to \$4.70.

One analyst said he considers the company stronger because it can focus its money on a more promising drug.

"For investors who were hoping the Efaproxyn study would be positive, obviously the announcement is a disappointment," said Jason Kantor, analyst for San Francisco-based RBC Capital Markets. "We had anticipated that this trial would fail, so from my perspective it makes an investment in Allos much more attractive because they're now focusing all their resources on the more interesting product, PDX."

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