

"The Pink Sheet" **DAILY**

May 26, 2009
Number 001

Amgen Elects Option On Cardiac Drug, Improving Cytokinetics' Strong Cash Position

Only a week after bringing in \$14 million from a registered direct offering of stock, Cytokinetics grew even wealthier on May 26 as Amgen elected to take its option on worldwide rights (except for Japan) to Phase II heart failure drug CK-1827452. The big biotech's decision triggers a license payment of \$50 million.

A novel, small molecule cardiac myosin activator, '452 was the primary asset anchoring a 2006 deal between Amgen and Cytokinetics for cardiac contraction therapies (¹Windhover's Strategic Transactions Database, January 2007). That deal brought South San Francisco, Calif.-based Cytokinetics \$75 million upfront. The biotech could realize up to \$600 million in pre-commercialization milestones. While details are unavailable, the majority of those milestones are tied to regulatory development of '452.

The news sent Cytokinetics' stock price on an incline, as it finished trading May 26 up 25 percent to \$2.61. That price is noteworthy because of warrants included in the firm's May 19 shelf takedown with long-term institutional investors. The investors purchased 7.1 million common shares for \$1.97 in a deal that also included a 30-day warrant for 0.5 shares per full share purchased.

The warrants were structured so that if Amgen elected its option, the additional shares could be purchased for \$2.75 apiece within 30 days of the offering's May 21 closing. With Cytokinetics' share price already nosing up close to \$2.75, the investors may be able to cash in those warrants at a discount. The investors also had a downside guarantee of being able to buy the additional shares at as low as \$1.50 if Amgen declined its option.

In an interview, Cytokinetics CEO Ronald Blum estimated the offering resulted in a 15 percent dilution of the company's stock. "Certain long-term value and growth-oriented investors with our company ... said 'we'd like to get a larger position ahead of the Amgen decision,'" he said. "We didn't raise a lot of money ... but for us that's a nice insurance policy were Amgen not to exercise and as such we bought ourselves some additional runway."

Runway into 2012 a possibility

Runway should be no concern to Cytokinetics for the next couple of years, especially since Amgen takes over all development costs related to '452 as part of the transaction. On April 30, the biotech reported its first-quarter financial data, citing cash and equivalents on hand totaling \$81.4 million.

Add in the \$14 million from the registered offering and the \$50 million due from Thousand Oaks, Calif.-based Amgen and Cytokinetics is looking at a balance sheet with about \$145 million to advance its ongoing programs in muscle-function biology and oncology. During an investor call May 26, Cytokinetics CFO Sharon Barbari said the license fee was due from Amgen within 30 days and would be recorded as second-quarter 2009 revenue.

The firm added during the call that it is in talks with multiple Japanese companies to license rights for '452 in that country.

Amgen takes over a development program with two Phase IIa trials still running and a Phase IIb program expected to begin during the second half of 2009. Blum noted that development will be coordinated between Amgen and Cytokinetics, with his firm continuing to do some of the clinical work, with all related expenses being reimbursed by Amgen.

Transfer of '452 development costs removes about 40 percent of Cytokinetics' cash burn from its balance sheet, Blum

said. The biotech also holds an option to reinvest some of its milestone payments, the first of which would be triggered by the start of the Phase IIb program, into late-stage development of the drug in fixed-dollar increments.

"So [our deal is] in contrast to a lot of deals where companies might have a tiger by the tail, they have to pay a percentage of costs and that percentage can be a floating absolute number because the costs could be increasing over time," he explained.

This deal structure differs from the Amylin/Lilly co-development and co-promotion deal that has led to investor Carl Icahn's concerns about Amylin's financial acumen. Contrary to the recent past, biotech investors now seem to prefer deals in which firms offload costs rather than deals in which they share costs but retain clinical control of the program.

This option also permits Cytokinetics to share in North American promotion of '452, taking on the sale of the drug in the institutional setting, with Amgen again reimbursing related costs.

Lazard Capital's Joel Sendek lauded the deal from Cytokinetics' perspective in a May 26 note, estimating it would leave the company with sufficient funds to continue its other programs into 2012. The risk for Amgen and investors, he said, is that '452 acts on novel targets that haven't been validated in large-scale trials.

Program so far consists of small, successful trials

Cytokinetics advanced the '452 program with a series of small Phase I and Phase IIa studies ("The Pink Sheet" DAILY, April 29, 2008). One tested an IV formulation in five cohorts of eight patients, while an ongoing trial tests 90 patients with ischemic cardiomyopathy and angina with both oral and IV dosing.

"We're quite fortunate in that we can develop both an IV and an oral [formulation]," Blum said. "We're doing that for both offensive and defensive purposes. From the offensive side, this allows us to capture patients when they are at highest risk and hot, with acute heart failure."

He explained that new cardiac drugs are difficult to test because many heart failure patients improve under hospital care due simply to bed rest and treatment with diuretics. The hospital mortality rates for such patients range between 1 percent and 2 percent, but that doesn't necessarily lead to improved outcomes down the road. Indeed, post-discharge, 30 to 40 percent of heart failure patients are readmitted to the hospital; another 20 to 30 percent will die from their disease.

With that in mind, '452 is being developed as an IV drug for the hospital setting and an oral therapy for continuing care after discharge.

"If you have a drug that is both intravenous and oral and you can develop them as part of a coordinated regimen," Blum continued, "then you have the potential in a clinical trial to assess when patients are at highest risk and longitudinally over a period of time so that you can hopefully in a statistically robust way demonstrate clinical benefit more predictably."

-Joseph Haas (j.haas@elsevier.com)

"
"

Contents copyrighted © F-D-C Reports, Inc. 2009; protected by U.S. Copyright Law.

"

Tgr tqf vevkqp. 'r j qvqqr { lpi . 'uxqci g"qt"tcpuo kukqp"d{ "o ci pgve"qt"grgevtqple"o gcpu'ku'utlevn{ 'r tqj kdkgf"d{ 'rxy 0Cwj qtq cvkqp"vq" r j qvqqr { 'lgo u'ht'kpvgtpcn'qt' r gtuqpcn'wug'ku'i tcvp'gf"d{ 'H/F/E'Tgr qtvu."kpe0'y j gp'vj g'hgg'qh"&4702'r gt'eqr { 'qh gcej 'r ci g'ku'r ckl" f lt gev' "vq'Eqr { tki j v'Ergetcpeg'Egpygt."444'Tqugy qqf 'F t0'F cpxgtu."O C"23; 45."*; 9: +972/: 6220Xkqr v'kqp"qh'eqr { tki j v'y knit guwn' kp'ngi cr'ce'v'kqp.'kpenf lpi 'ek'kl'cpf lqt'etko kpcn'r gpcn'kgu.'cpf "uwur gpukqp"qh'ugt'x'le'g'0Hqt"o qt'g'lphqto cvkqp.'eqp'cev' hf etgr tlpvuB gngx'kgt@qo 0