

BIOTECH / by Daniel S. Levine

Cytokinetics pumped about heart drug deal with Amgen

For emerging biotechs that hope to some day commercialize their own products, balancing financial needs with lofty ambitions can be tough.

The concern is giving away too much too soon, particularly when capital markets are not feeling the love and big-name partners courting with checkbooks are at the ready. While some companies are content serving as a farm system for big pharma, others have their eyes set on the show.

The recent collaboration Cytokinetics entered into with biotech giant Amgen is an example. The South San Francisco biotech will still control development of its first-in-class drug for patients with chronic heart failure and will use the deal — if the drug makes it to market — to propel itself into a commercial enterprise and let Amgen foot the bill.

“It has the potential, if the product is going to be successful, to have them effectively financing our migration from an R&D organization into a fully integrated commercial enterprise,” said Robert Blum, president of Cytokinetics.

Unusual deal

The deal over Cytokinetics’ drug candidate for heart failure and potential related compounds provides \$42 million in upfront payments and carries the potential for \$600 million in milestones with the success of the lead compound alone. Amgen also purchased \$33 million in Cytokinetics stock — nearly 3.5 million shares at \$9.47 a share — roughly a 7.5 percent stake in the company. The deal covers worldwide rights for the drug, excluding Japan.

But the deal is a bit unusual. Rather than taking charge of development of the drug, Amgen has paid for an option to participate in future development and commercializa-



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tion of the lead candidate in the collaboration. During the initial two-year research term, Cytokinetics will perform research and continue to conduct all development activities at its own expense.

After Cytokinetics conducts proof of concept trials, if certain pre-defined criteria are met, Amgen will pay an exercise fee of \$50 million and will take responsibility for further development and commercialization.

The deal calls for Cytokinetics to earn double-digit royalties that escalate based on increasing levels of annual net sales of products commercialized under the collaboration. The company could increase those royalties by picking up part of the tab for late-stage development.

Should it do that, Cytokinetics will have the right of co-promotion under the agreement, but Amgen will have responsibility for all manufacturing, marketing and related cost that could add up to hundreds of millions of dollars. Cytokinetics would focus on hospital and acute care setting markets, and Amgen will reimburse it for its sales-force costs.

Last fall, Cytokinetics released promising results from a first-in-human, early-stage clinical trial that provided hope that its cardiac myosin activator drug strengthened the pumping of the heart, without causing life-limiting side effects found with existing drugs.

Cardiac myosin is the motor protein in the cardiac muscle cell that converts chemical energy into the mechanical force that results in contraction of the heart.

Drugs used today to treat heart failure work by elevating calcium levels, which also increases oxygen consumption and can raise blood pressure and cause irregular heart beat. Though patients feel better, side effects can cut their longevity.

‘Transformative’ deal

Blum said one of his concerns in doing deals is to have proof-of-concept in hand to ensure partners’ interests are aligned as a compound advances to late-stage development. In the case of Cytokinetics heart failure drug, the company has encouraging early-stage data, but has not yet conducted a proof-of-concept trial.

He said by selling Amgen an option, Cytokinetics retains control of development of the drug and can use the money where it thinks it’s best spent and take advantage of the clinical development capabilities it has.

At the same time, he believes that the deal gives the company terms that are consistent with returns from late-stage deals of comparable value and for products of similar market potential.

“It is a deal that we consider to be quite transformative,” said Blum. “We think the economics are quite unusual.”

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