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NGM Aims For Three Drugs In Clinical Trials, Padded By Cash From Merck

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Executive Summary

Privately held NGM Biopharmaceuticals is investing in another dozen preclinical compounds, fueled in part by a rich deal with Merck & Co. that also enables employee expansion, Jeff Jonker explains in interview.

NGM Biopharmaceuticals Inc. is in the midst of a big growth spurt, funded largely by a lucrative deal the privately held drug developer signed with Merck & Co. Inc. last year. The company is adding human resources, with an emphasis on research, planning a move into a new larger headquarters and is on track to have three of its assets in clinical development in 2016.

President Jeff Jonker talked about the firm's transformation since signing the deal with Merck during an interview at the J.P. Morgan Healthcare Conference Jan. 13.

"The Merck deal really allows us to think pretty expansively and work expansively," Jonker said. "It is really fulfilling the vision we have of building out a robust R&D engine and the kind of company that is going to be able to sustain that for a long time."

The company has grown from 70 people before the Merck deal was signed in February 2015 to 110 people currently and is on track to continue growing to 150 to 160 people by the end of 2016, with

"I don't have a cash-out date. It would be somewhere in the 2020s," Jonker said of the company's $275m cash

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almost all of the new recruits joining in research. The company is also moving into a new 125,000-square-foot custom-outfitted headquarters, with 80,000 square feet of laboratory space, in South San Francisco.

stockpile and research funding from Merck.

But what Jonker is most enthusiastic about is the company's ability to invest more in drug development and advance the early pipeline.

"Had we been a small company focused on cardio-metabolic disease, we would have had to concentrate our energy on one or two of the clinical programs and then really narrow down the preclinical work as well to the ones we thought had the highest probability, or the best return for our investment," Jonker said.

Instead, thanks to the cash coming from Merck, NGM is advancing all of its programs, including three in the clinic in 2016 and about a dozen in preclinical development.

NGM is developing biologics, with an initial focus on cardio-metabolic disease, but with interest across a broad range of therapeutic areas, including oncology. The company has been working under the radar and holding its technology close to the vest, but its drug development efforts are focused on targets that have been previously unknown or considered "undruggable."

"I'd love to tell you that we have something called the druginator that spits stuff out and it is only ours, but that is not quite right," Jonker said. "We have a very old-school style of discovering biology."

A Storied Pedigree

The company was founded in 2008 following a $25.5m Series A financing, by Jin-Long Chen, who was previously VP-research and head of metabolic disorders at Amgen Inc. and before that VP-biology at Tularik Inc. Many of the researchers at NGM are Amgen and Tularik alums. The company has had some high-profile supporters, including former Genentech Inc. CEO Arthur Levinson, who was an early director of the company.

The deal with Merck also has ties to Amgen, since Merck's R&D chief Roger Perlmutter previously led R&D at Amgen and knew many of the researchers working at NGM.

Under the wide-ranging deal, Merck gained access to most of NGM's pipeline, with an option to license assets after Phase II proof-of-concept. NGM retained its lead asset, NGM292, in clinical development, while Merck licensed outright the preclinical "diabesity" program NP201, potential treatments for diabetes, obesity and the liver disease non-alcoholic steatohepatitis (NASH). In exchange, Merck acquired a 15% equity stake in NGM for $106m, paid $94m upfront and agreed to pay $250m in R&D funding over five years ("Merck Essentially Options A Pipeline In Collaboration With NGM" — *"The Pink Sheet" DAILY*,Feb. 24, 2015).

The deal was uber-competitive, which is partly why NGM got so many of the terms it wanted, like a 50/50 profit-share option on drug candidates.

The companies were originally in licensing discussions for one program, according to Jonker, but the deal morphed into a larger opportunity after Merck

lost the negotiation to a rival.

“Roger Perlmutter called us and said I’d like you to reconsider your position and I’d like to talk,” Jonker said, noting the R&D chief jumped on a plane and the two companies hashed out the final deal over the weekend.

First Merck Programs Enter The Clinic

Merck’s NP201 program is made up of two drug candidates, a once-daily drug NGM386 and the longer-acting NGM395, targeting a human hormone discovered by NGM expressed by tissues involved in metabolic functions, including the liver, and essential to reducing weight and normalizing blood tissue. Merck is leading development of the compounds, in coordination with NGM. NGM386 will be entering the clinic in 2016, with NGM395 on track to follow shortly after, Jonker said.

The other programs involved in the collaboration will be overseen by NGM through proof-of-concept. Another molecule, NGM313, a humanized monoclonal antibody engineered to agonize or activate the beta-klotho-FGFR1c receptor complex involved in the regulation of weight, triglycerides and cholesterol, will enter the clinic in the first quarter.

NGM’s wholly owned NGM282 is an engineered version of human FGF19 hormone, a regulator of bile acid synthesis in the liver and a key signaling molecule in metabolic processes. FGF19 has been targeted by the industry in the past, but overexpression of the hormone has been linked to liver tumors in mice, so the target has been largely abandoned by the industry, according to NGM. The company’s engineered version has therapeutic effect without the proliferation that can lead to the nasty off-target effects.

A Phase II study in patients with NASH is ongoing and will read out in 2017. The company also expects to initiate another Phase II study this year in patients with primary sclerosing cholangitis (PSC), an orphan indication.

NGM completed Phase II tests in primary biliary cirrhosis (PBC), with solid safety and efficacy results, but has opted not to continue developing the drug for that indication, given the competitive environment. Intercept Pharmaceuticals Inc. has a PDUFA date approaching Feb. 29 for its obeticholic acid (OCA) for the treatment of PBC.

The pending product appeared to have played a role is NGM's decision to discontinue development in PBC. “The question is if you are relatively comparable and maybe in a less-convenient presentation is that really the best place for that therapeutic,” Jonker said.

“So what we are exploring is a very similar disease, primary sclerosing cholangitis, where there are no approved therapies. It has a similar biology and there is reason to believe, from preclinical experience, that it actually has a better effect in that disease than some of the other agents that have been tested.”

NGM has plenty of financial bandwidth to fund the company’s expansion strategy, with $275m in cash, thanks to Merck and a series of successful financings, and Merck picking up the tab for most of the company’s ongoing research.

That means NGM is in a rare position in the world of biotech. “I don’t have a cash-out date. It would be somewhere in the 2020s and I don’t even know,”

Jonker said.

So a move to the public markets won't happen anytime soon. "We will be much more opportunistic about when we go," he said. "I think it is going to be at a time when the markets are looking good, when I think we have a story, including data, that we are prepared to share that will really get people enthusiastic."