BIOWORLD™
The Daily Biopharmaceutical News Source
Now From Thomson Reuters

Five Prime Therapeutics, BMS deal: $20M up front, equity stake in checkpoint bid

By Randy Osborne
Staff Writer

Tuesday, March 18, 2014

Five Prime Therapeutics Inc. is getting $20 million up front, selling a premium-priced equity stake, and "learning from the masters, as it were," in its three-year cancer immunotherapy deal with Bristol-Myers Squibb Co. (BMS), an agreement centered on two undisclosed pathways that could generate a couple of targets each, said Five Prime CEO Lewis Williams.

BMS, of New York, paid $21 million for 4.9 percent of Five Prime's outstanding shares, bought at 30 percent above the going rate, and has pledged as much as $300 million per target in milestone payments related to development, regulatory, and sales goals. If products result, Five Prime stands to collect tiered mid-single-digit to low-double-digit royalties. The research term of the deal could be extended up to two more years.

Five Prime's stock (NASDAQ:FPRX) closed Monday at $22.99, up $4.22, 22.6 percent.

"We've been building this platform over the years," Williams told *BioWorld Today*, and it includes a library of 5,700 proteins found on the surfaces of cancer cells or immune cells, plus screening that's done by a cell-based, automated process, or in vivo using mice.

"Either one by itself would be a unique resource, but the combination is what's powerful," Williams said. "We've demonstrated this before in other fields," and recently reorganized for the push in cancer immunotherapy. "That was a very deliberate move on our part, because we saw we had a special advantage," he said, though "it was kind of under the radar screen until recently. Even at the time of our initial public offering [IPO] last September, this wasn't the featured program. We're sort of out of the closet now, in terms of our focus."

In its IPO, South San Francisco-based Five Prime increased its prospective number of shares by 8 million, selling a total of 4.8 million shares at $13 apiece, the midpoint of its proposed range, to raise gross proceeds of $71.8 million, after underwriters exercised their overallotment option. (See *BioWorld Today*, Sept. 19, 2013.)

BMS data have already shown that "when you combine two checkpoint inhibitors, you get an effect that's bigger than either alone, and those effects appear to be long-lived," Williams said,

adding that Five Prime aims to find new targets for single agents. “The checkpoint inhibitor area is the realm of protein drugs, not small molecules, and we only work on protein drugs – antibodies and antibody-like molecules, like ligand traps,” which puts Five Prime in the “sweet spot” of cancer immunotherapy, he said.

Another boon: Five Prime’s main areas of interest are cancer and inflammation, and the immune system – boosting or knocking it down – is important in both. “What you learn about each side of that coin can help you with the other side,” Williams said.

Aron Knickerbocker, chief business officer of Five Prime, said the success of BMS’ melanoma immunotherapy Yervoy (ipilimumab) lit a fire under the checkpoint field. “The responses seen with Yervoy can be very durable but occur in the minority, still, of patients treated with the agent,” he said. “I think what we’re looking at here is a resistance mechanism. The tumor cells have figured out ways to evade surveillance by the immune system and disguise themselves as self. The CTLA4 axis that Yervoy acts through is just one. PD-1/PDL-1 is another.”

FUEL FOR THE PIPELINE

CEO Williams noted that melanoma represents “a cancer in which there’s a long history of attempts to enhance the immune system’s ability to attack melanoma cells.” Because the tumor features many mutations, “there just haven’t been good therapies available until the checkpoint inhibitors came along,” he said. “Some of the early data [in squamous cell lung cancer] look promising as well,” Williams said, and immune stimulation by way of interleukin-2 (IL-2) has proven encouraging in kidney cancer. IL-2 “doesn’t have a high response rate, but [among] the few who respond, some of them have a good response,” he said.

“I think most people in this field believe that over the next few years we’ll see other tumors come into play,” Williams said. “It’s a little hard to predict how many and which ones.”

Knickerbocker told *BioWorld Today* the BMS deal “really fortifies our balance sheet” and leaves Five Prime “well positioned to get through several inflection points,” since the financial runway extends more than two years, long enough to yield “several data readouts in our current programs.”

With partner Glaxosmithkline plc, of London, Five Prime has the fibroblast growth factor (FGF) inhibitor FP-1039 in phase Ib trials for solid tumors. FPA008 is an anti-CSF1R antibody, which we designed to block the ability of IL-34 and CSF1 to bind to and activate CSF1R, thus reducing inflammation in conditions such as rheumatoid arthritis. It’s in phase I trials, with data expected by the end of this year. FPA144 is a monoclonal antibody directed against a form of FGF receptor 2 known as FGFR2b, and Five Prime aims to begin a phase I trial in the second half of 2014 in patients with tumors expressing high levels of FGFR2b. Preliminary data likely will be available by the end of 2015.

Wells Fargo analyst Brian Abrahams, who predicted last week that Five Prime would disclose a partnership soon, wrote in a research report about the BMS deal that the news was “not entirely surprising, given Five Prime’s openness about hopes to sign a collaboration” since the change in

direction toward cancer immunotherapy. Still, the news “should help improve visibility for what we view as an underappreciated pipeline and technology platform,” Abrahams wrote.