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Fear not: Sofinnova backs 'Dauntless' approach to drug development

By Marie Powers, News Editor

Dauntless Pharmaceuticals Inc. had a smooth initial take-off, fueled by a $12 million series A supporting a single asset, and that's just the way the San Diego-based company and backer Sofinnova Ventures plan to keep rolling off the runway. Rather than scattering resources across a portfolio of early stage assets like so much fairy dust, Dauntless plans to house each in-licensed candidate in a separate holding company with its own budget and development goals.

The concept grew out of the frustration of trying to extricate individual assets that biopharmas wanted to license or acquire from intermingled pipelines in various stages of development, with investors, management, labs and staff collectively sharing interest in everything, explained Mike Powell, Sofinnova general partner, who serves as co-founder and chairman of Dauntless.

"With this model, we are developing different assets and putting each into its own shell," Powell said.

The Dauntless management team largely transitioned from Cebix Inc., also a San Diego-based Sofinnova portfolio company, following its shutdown at the end of January after its once-promising diabetes drug missed in phase IIb. (See *BioWorld Today*, Oct. 18, 2012.)

Despite the disappointing outcome, Powell praised the company's leadership and was eager to work with the group again. Co-founder Joel Martin, a serial entrepreneur who was president and CEO of Cebix and serves in the same roles at Dauntless, had the same thought, and the formation of Dauntless moved with breathtaking speed.

Named for the intrepid scout plane and dive bomber that was a mainstay of the U.S. Navy's Pacific air fleet in World War II, Dauntless plans to manage the development of each asset using a core group of employees supplemented by a larger stable of consultants. Sofinnova was the sole investor in the series A – "a first for us," Powell said – designed to power the initial asset, DP1038, through proof-of-concept studies in endocrine cancers using the 505(b)(2) pathway.

Dauntless is keeping details close to the vest, but Martin said the focus of DP1038 is to develop a "friendlier" way to deliver cancer drugs to patients. In conjunction with the series A, the company reported a licensing agreement with Aegis Therapeutics LLC granting access to its Intravail drug delivery technology for an undisclosed oncology application, with an option for three additional drugs. Terms were not disclosed.

"It's a big-market drug and the technology looked compelling and free of any obvious safety issues," Martin said, noting the mechanism offers the potential to improve the delivery and stability of other late-stage assets.

"We were excited about the commercial opportunity and the early clinical data using this technology with other drugs," he said.

The series A round is designed to take the company well into phase II, according to Powell, who said Sofinnova is "agnostic" about its funding amounts, provided they accomplish the job at hand.

"We tell each company to pull together a budget for whatever needs to be done," he said.

'WE WILL NOT BE A DISCOVERY COMPANY'

Dauntless is casting a wide net to build its stockpile, "but we will not be a discovery company," Martin emphasized. "We've done a lot of preclinical development work, and we've managed those programs and timelines very effectively. But we don't have a lab, and we're not going to do screening against targets."

Although Dauntless will leverage the 505(b)(2) route whenever possible, "that's probably a limited universe" of candidates, he acknowledged.

The company is already talking with several midsize to big biotechs about additional in-licensing opportunities, including compounds to treat cancer and orphan indications.

The "touchstone," Martin said, is the feasibility of conducting clinical trials, with an indication such as Alzheimer's disease "outside our financing reach."

Biotechs are "more facile" in negotiating those licensing arrangements, due to interpersonal relationships in the industry "and the comparatively lower bar toward inertia," he added. "We are reaching out to pharmaceutical companies, but that's a longer process."

No matter which route Dauntless takes to assemble its portfolio of assets, "the goal here is to add value to these assets and send them on their way," Martin emphasized. "We're just being realistic about how much capital we can raise. At a certain point, the assets need to move on."

Although Martin and Powell expect to build Dauntless gradually and deliberately, additional investors already are contacting the newco to learn more about its model and development strategy. Sofinnova likely will play a lead role in future financings unless there's a conflict with the firm's other holdings, but both sides of the table welcome other comers.

"We have a pretty good sense of what's reasonable, and we drive pretty hard timelines with outside providers," Martin said. "The value here for investors and for companies that bring us assets is that we have the existing infrastructure and skill set to develop these assets without the kind of fixed costs you normally have in setting up a company. We're ready to go."

Long term, Dauntless also hopes to grow into a sustainable organization. Although Martin started in academia and co-founded or led companies such as Altair Therapeutics Inc., Quantum Dot Corp. and Argonaut Technologies, along with tenure at three major VC firms, he's not a huge fan of the single-asset play that results in a company's dissolution once that compound is acquired.

"That's a tremendous waste of human capital," he said. "We think the Dauntless model capitalizes on building a very, very strong and efficient team for the long run."