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Off the beaten path

Cincytech sells southwest Ohio to the world in San Francisco

By Marie Powers, News Editor

John Rice is a veteran of the annual J.P. Morgan Healthcare Conference (JPM), dating back to the days when it was known as Hambrecht & Quist. He's accustomed to the frenetic pace of the San Francisco event that kicks off the year for biopharma and, increasingly, for the larger life sciences universe. What's different from those early years is the number of costume changes he makes during the week as director of life sciences at Cincytech.

A public-private seed stage investor currently investing out of its $30.75 million Fund IV, Cincytech has an active portfolio of companies in life sciences and digital health care along with business software applications, technology-enabled services and digital consumer and marketing technologies.

Cincytech is supported by Ohio Third Frontier and more than two dozen foundations, corporations, municipalities and individuals in southwest Ohio, as well as founding partners Cincinnati Children's Hospital Medical Center, the University of Cincinnati and the Cincinnati USA Regional Chamber.

In this year's meetings at JPM, Rice mainly was representing biopharma portfolio companies Airway Therapeutics LLC, Invirsa Inc. and Myonexus Therapeutics Inc. and med-tech firms Enable Injections LLC, Genetesis and Eccrine Systems Inc. Most of the companies also had their own teams working the Union Square neighborhood, in all taking dozens of meetings over three days.

Rice also was happy to entertain questions about Aerpio Pharmaceuticals Inc., a 2011 spinout from Akebia Therapeutics Inc., also based in Cincinnati at the time. Aerpio generated traction by landing a $27 million series A in 2012 and subsequently moving lead candidate AKB-9778 into the clinic. The Tie2 activator is now in a phase IIb study in non-proliferative diabetic retinopathy (NPDR). The small molecule inhibits receptor-type tyrosine-protein phosphatase beta, or VE-PTP, a critical negative regulator of Tie2 in diseased blood vessels. Last year the company completed a reverse merger and raised another $40 million to fund the asset's late-stage development. (See *BioWorld Today*, March 17, 2017.)

Rice is optimistic about similar success with the younger therapeutic efforts. Although Cincinnati doesn't have the deep pockets of Boston or Silicon Valley, "we look for the best life science deals we can find," with solid research, capital-efficient structures and talented leadership, Rice told *BioWorld*. "There are plenty out there."

Good deals attract venture funding, even in Cincinnati, he added.

"Nobody cares about geography anymore," Rice insisted.

Cincytech places about $1 million or thereabouts in seed funding to last about 12 months and participates in subsequent rounds, which often attract national and ex-U.S. investors. The seed fund takes the role of "subjective" investor, helping to nurture its portfolio companies and position them for additional development, but steers clear of day-to-day oversight.

"We're maybe not unique, but we're successful because we can syndicate our portfolio companies" and "curate" deal flow, Rice said.

Strategic decisions depend on 'the appetite of investors'

Founded in 2011, Airway is one of the few companies developing a synthetic protein, known as AT-100, designed to prevent bronchopulmonary dysplasia (BPD), a chronic lung disease that develops in preterm infants who require ventilation shortly after birth. The recombinant human surfactant protein D (SP-D), in-licensed from Cincinnati Children's, also may have applications to prevent and treat respiratory distress syndrome, including pneumonia and asthma in premature infants.

AT-100 SP-D protein replacement therapy works by stabilizing the lungs and supporting the immune system. Unlike surfactant therapy, AT-100 has anti-infective and anti-inflammatory properties and has an effect on surfactant homeostasis. Nearing the completion of preclinical development, the agent has orphan designation for prevention of BPD in the U.S. and Europe.

Both the FDA and EMA have endorsed, in principle, moving AT-100 directly into a phase II safety and efficacy study, followed by a single randomized phase III, before proceeding to filings.

In 2014, Airway secured $4.6 million in a series A round led by Cincytech with participation from Cincinnati Children's, Queen City Angels and private investors. The company added $6.3 million in financing last year and inked an exclusive licensing agreement with German biotech Glycotope GmbH for global commercial rights to Glycotope's cell line technology, Glycoexpress, to produce AT-100.

Managing preterm neonates is a cornerstone of the R&D

at Cincinnati Children's, "so we basically took one of the key projects to move forward and develop in a way that's consistent with regulatory body expectations and with industry development pathways," Marc Salzberg, Airway's president and CEO, told *BioWorld*. Airway intends to build "a prolonged line" of assets from Cincinnati Children's with the goal of improving outcomes for neonates. Management of BPD in infants is estimated to cost more than $2.4 billion annually in the U.S., alone, he pointed out, not to mention the social and emotional aspects of the condition, which prevent new mothers from even holding their infants.

"I've been in drug development for over two decades," said Salzberg, whose career included tenure in drug development at the headquarters of Roche Holding AG in Basel along with work in academics and at a CRO. "I've rarely seen a situation where you have so many experts and key players in a field – academic and industry collaborators – endorse a project so substantially."

Along the way, Airway added to the technology's intellectual property portfolio. The desired end game for the single-asset "build to buy" company is a partnership with an option deal or straight-out acquisition, according to Rice.

"We're willing to partner before phase III," he said. "We'll look at that as we get close. We might decide to wait because this is a relatively short development time and relatively less expensive development program, so we may fund all the way to launch. But do we want to run a company? Those are the kinds of discussions that go on around the table, and the decision will depend on the appetite of investors, where they are with their funds and what they're doing strategically."

Columbus, Ohio-based Invirsa is one of Cincytech's newer portfolio holdings. Lead candidate, INV-102, derived from a naturally occurring small molecule, strengthens the innate immune response and stimulates the repair of damaged DNA. In vitro tests have suggested that INV-102 reduces cellular injury or death caused by adenovirus – the main virus associated with the lead indication of infectious conjunctivitis. Still in discovery, the small molecule may have an additional application to treat upper respiratory tract infection.

Last year, Invirsa closed $520,000 in seed financing led by Cincytech with participation from Rev1 Ventures. CEO Robert Shalwitz, a pediatric endocrinologist who led teams to successful NDA and sNDA filings at Abbott Laboratories (now Abbvie Inc.) and Reliant Pharmaceuticals Inc. – sold in 2007 to Glaxosmithkline plc for $1.65 billion – also is a known quantity to Cincytech as a co-founder of both Akebia and Aerpio.

At JPM, Rice was seeking interest from investors for a financing to take Invirsa through IND-enabling studies and to an IND filing. The plan is to fund the company through clinical proof of concept – a milestone that can be achieved relatively quickly through short-duration studies – then determine whether to finance through product launch, co-found with a partner or seek an exit through an IPO or M&A. The technology offers a differentiated profile from other types of infectious disease agents, Rice said, because it promotes natural resistance.

Myonexus, of New Albany, Ohio, completed a $2.5 million seed financing late last year in which Cincytech, Rev1, the Jain Foundation and GFB ONLUS joined initial investors from the limb-girdle muscular dystrophies (LGMD) community. The company is advancing a pipeline of five gene therapy candidates, two of them already in the clinic. The assets were pioneered in the lab of Louise Rodino-Klapac in collaboration with fellow researcher Jerry Mendell, both principal investigators at Nationwide Children's Hospital Center for Gene Therapy in Columbus.

The seed financing will enable Myonexus to move a third candidate, MYO-101, into the clinic early this year in a systemic phase I/IIa trial targeting LGMD2E, or beta-sarcoglycanopathy. MYO-102 is completing a phase I/II trial to treat LGMD2D (alpha-sarcoglycanopathy), and MYO-201 is in a phase I study targeting LGMD2B (dysferlinopathy). MYO-103, targeting LGMD2C (gamma-sarcoglycanopathy), and MYO-301, for LGMD2L (anoctamin 5) remain in preclinical development.

LGMD comprises a group of monogenic diseases that cause weakness and wasting of the muscles in the arms and legs, especially those closest to the body in the shoulders, upper arms, pelvic area, thighs and, occasionally, the heart. The Myonexus candidates represent the first gene therapy efforts targeting LGMD types 2D, 2B, 2E, 2L and 2C. Researchers at Nationwide Children's advanced their adeno-associated virus platform by leveraging the same discovery, preclinical R&D, GMP manufacturing and clinical trial capabilities that supported development of other gene therapy and neuromuscular disease-focused companies with which they had relationships, including Avexis Inc. and Sarepta Therapeutics Inc., Rice said.

At JPM, he was assessing interest in venture funding, strategic partnerships and crossover investment to bridge to a potential IPO in the hot technology space. Myonexus expects to report its first data this year.

Rice doesn't expect to run out of life science prospects in Cincinnati anytime soon, and Cincytech is already discussing plans for its next fund.

"We have an institutional partner in Children's that is probably one of the best-kept secrets in the country as a powerhouse research institution, in terms of quality and amount of funding," he said. "When you have partnerships within a state and a supportive community, you can make good choices that lead to good investments."