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Bridging the Valley of Death

University Hospital seeks to fund physician-scientists and develop their discoveries through non-profit and for-profit entities

By Daniel S. Levine

The valley of death, the term used to describe the wasteland where discoveries too early in the development process to attract industry or venture funding but too advanced to attract government backing, is well known to physician-scientists. Though a variety of initiatives in recent years has tried

to address the gap in funding translational research, the difficulties in commercializing discoveries is often made worse due to their lack of understanding of the development process. Now, though, a unique national effort by Cleveland's University Hospital is hoping to provide both guidance and funding to address the problem.

Backed with \$250 million in

philanthropic, university, and venture funding, the Case Western Reserve Medical School affiliated hospital system is taking an innovative, two-pronged approach to seeing inventions from the lab make it to the marketplace. The effort marries a non-profit, grant making entity named University Hospitals

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Improving Market Drives Life Sciences Financings in February

The strong boost to biotech stocks in the first two months of the year sparked new life in the sector and allowed companies to raise new funding in public markets. Of the 340 life sciences

Month In Review

companies trading at or above \$1 at the end of 2011, 257 or 76 percent of them are trading higher

year-to-date while 26.4 percent of those companies are up more than 25 percent so far this year. On the other end of the spectrum, 26 percent of these companies are down year-to-date, with only 2.6 percent of those companies falling more than 25 percent. In February, all of the Burrill Indices ended the month higher with the Burrill Biotech Select Index up 15.88 for the year. The Dow Jones Industrial Average, up 6.26 percent for the year, closed above the 13,000 mark in February, the first time since 2008.

There was a sharp improvement in the price of life sciences stocks as economic news in the United States has been generally positive this year, actions in Europe to address the debt crisis advance, and news within the sector is encouraging. However, in

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Life Sciences Capital Scorecard in USD M, through Feb 29, 2012

	2012	2011	Change		2012	2011	Change
Global Venture Capital	2,138	1,497	42.8%	Global Debt Offerings	2,624	5,617	-53.3%
U.S. VC	1,325	1,005	31.8%	U.S. Debt	2,232	4,967	-55.1%
IPOs (8 in 2012 v. 18 in 2011)	464	1,345	-65.5%	Global Other Debt	1,377	1,826	-24.6%
U.S. IPOs (6 in 2012 v. 8 in 2011)	380	521	-27.1%	U.S. Other Debt	1,364	200	582.0%
Global PIPEs	865	712	21.5%	Total Global Public Financings	7,196	11,366	-36.7%
U.S. PIPEs	365	284	28.5%	Total U.S. Public financings	6,084	7,039	-13.6%
Global Follow-ons	1,401	1,866	-24.9%	Global Partnering	8,895	9,269	-4.0%
U.S. Follow-ons	1,293	1,067	21.2%	U.S. Partner/Licenser	4,145	6,773	-38.8%
Global Other Equity	465	N/A		Global M&A	10,586	42,447	-75.1%
U.S. Other Equity	450	N/A		M&A, U.S. Target	9,459	33,591	-71.8%

Bridging the Valley of Death

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Harrington Discovery Institute and a for-profit accelerator that will select promising projects and carry them to proof-of-concept where they can then be licensed or spun-out to form new companies.

University Hospital says by aligning the non-profit and for-profit entities, it will, for the first time at an academic medical center, provide a comprehensive model to advance discoveries into development and create novel drugs and therapies for patient care. The Harrington Project is named for the Harrington Family, owners of Edgepark Medical Supplies. The family donated \$50 million to fund the project. The program will not be limited to people affiliated with University Hospital, but will reach out to physician-scientists nationwide.

"The current system nationally has been flawed, and we believe this new initiative is the solution," says Achilles Demetriou, chief operating officer of University Hospital. "One of the challenges that we have today is that many biomedical discoveries end up staying on the shelf; they never get commercialized. Through the Harrington project, we are providing a mechanism for physician-scientists to function in a structured environment where they can be challenged, coached, and supported to develop their insights into therapies."

University Hospital isn't alone in trying to address the gap. The National Institutes of Health has in recent years placed a growing emphasis on translational research, an answer to criticism that the massive investment in basic research was failing to yield enough in the way of returns in the form of new products benefitting patients. These efforts include the launch at the end of 2011 of the National Center for Advancing Translational Sciences, which is charged with working with the public and private sector to reengineer the translational research process.

At the same time, a variety of efforts from venture capital firms have sought to take new approaches to funding translational research, bypassing traditional company formation and in-

stead using virtual models to carry compounds to proof of concept. And then there's Big Pharma, which has struck a spate of discovery-stage alliances with universities in an effort to address the translational gap and its own R&D problems.

Jonathan Stamler, director of the UH Harrington Discovery Institute and director of the Institute for Transformative Molecular Medicine at UH Case Medical Center and Case Western Reserve University School of Medicine, says that everyone is trying to fill the valley of death in their own way. "The bottom line: government, venture, and

As part of the Harrington Project, the for-profit accelerator will provide a vehicle for commercialization of the discoveries made by Harrington Scholars as well as other academic researchers. The company, with a CEO and management team in place, has raised its initial capital and is in the process of attracting additional investors and evaluating programs with an initial capital plan of more than \$100 million.

The accelerator will build a portfolio of high value, early-stage development programs and will leverage the extensive insights and networks of na-

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Achilles Demetriou, Chief operating officer, University Hospital

pharma are all trying to tackle this problem. We are saying for the first time that academic medicine needs to tackle the issue too. We need to come up with a model that fulfills and aligns with our mission, rather than having a model imposed on us."

The UH Harrington Discovery Institute will provide funding, mentoring, and an infrastructure to advance breakthrough, patient-inspired clinical research projects. Physician-scientists selected to be Harrington Scholars will receive funding in two-year intervals. They will also be provided with focused direction on the steps necessary to move a discovery forward through early-stage research to clinical development, training not currently provided to physician-scientists.

Stamler hopes that by reaching out to physician-scientists from around the country the program will also be able to engage the home institutions of the various Harrington Scholars they fund and foster cooperation between the institutions to improve translational research.

tional scientific and commercial advisory boards. It will advance programs to a stage of clinical development that will attract additional financial and industry partners. The company will be formally announced later this year.

"It's exciting from my own vantage as an industry observer. You are seeing in this model innovation that is occurring on both sides—the non-profit and for-profit—in an aligned fashion that enables these discoveries to really move forward to become patient therapies," says Baiju Shah, CEO of BioEnterprise, a Cleveland based accelerator focused on the life sciences that has been advising UH in establishing the for-profit part of its operation. He says one problem with other efforts to help academic scientists translate their discoveries is that they often fail to consider what to do when the research meets with success.

"That's where the for-profit development company is so unique," he says. "It's designed to pick it up to advance these things and take them further into development." ■