Finance & Investments

UNITY Biotechnology Announces $116 Million Series B Financing

UNITY Biotechnology, Inc. ("UNITY"), a privately held biotechnology company creating therapeutics that prevent, halt, or reverse numerous diseases of aging, today announced the closing of a $116 million Series B financing.

In addition, UNITY announced that Keith Leonard, 25-year biotech industry veteran and current executive chairman, will take on the role of leading UNITY as CEO. Founder and previous CEO Nathaniel "Ned" David, Ph.D., will become the company's president and focus on further developing the company's biology platform.

The UNITY Series B financing ranks among the largest private financings in biotech history and features new investments from longtime life science investors ARCH Venture Partners, Baillie Gifford, Fidelity Management and Research Company, Partner Fund Management, and Venrock. Other investors include Bezos Expeditions (the investment vehicle of Jeff Bezos) and existing investors WuXi PharmaTech and Mayo Clinic Ventures. Proceeds from this financing will be used to expand ongoing research programs in cellular senescence and advance the first preclinical programs into human trials.

Novartis Presses Pause on $12B-plus Roche Stake Sale

Analysts suggest Novartis could reap $12.5 billion to $14 billion for the 33% stake it holds in Roche but Swiss newspaper *Sonntagszeitung* says the sale has been “iced.”

Sonntagszeitung’s say the sale is ready to go, but Novartis has yet to move on it and that it might hang onto its Roche shares rather than cashing them.

Steady Q3 for Roche

Roche Q3 results were in line with market expectations, with revenues increasing 4.5% for the quarter to reach 12.48 billion CHF ($12.6 billion) - just short of the 12.55 billion analysts expected. The company confirmed its 2016 guidance, predicting low-to mid-single digit growth. Pharma growth was up by 2%, driven by Roche’s oncology products.

AstraZeneca Buys Amgen’s Colorado Plant for $64.5M

AstraZeneca is buying Amgen’s plant in Longmont, Colorado for $64.5 million following on the heels of its purchase of Amgen’s Boulder facility for $14.6 million last year.

It plans to use the Longmont plant to warehouse materials to support manufacturing operations there.

The Longmont facility had been used to produce the anemia drug Epogen, which Amgen stopped producing at the plant in 2014. The site has been for sale since June 2015.

CR Pharma in $2 Billion China IPO

China Resources Pharmaceutical Group (CR Pharma) will begin its IPO offering in Hong Kong with a view to raising up to $2 billion for investment and expansion.

Part of the state-owned China Resources Holdings group, CR Pharma is hoping to sell 1.54 billion shares at between HK$8.45 and HK$10.15, with the remaining 50% of earmarked for institutional investors.

China's aging population with greater healthcare needs and rising levels of personal income is a lucrative market for the pharma sector. However, suppliers are fragmented with thousands of domestic companies serving the market.

Larger firms such as CR Pharma are believed to be looking at purchasing smaller players, with the aim of adding to their own product portfolio and reducing cost bases.

CR Pharma is the second-largest domestic pharma company in China. Its brands include "999" and "Double Crane." CR Pharma also operates the ninth-largest retail pharmacy chain in the country, which is set to benefit from Chinese government efforts to shift the balance of power in drug distribution away from hospitals.

CR Pharma is also looking beyond its native land for growth opportunities. Earlier this year, it signed an agreement with Pfizer to re-pack and distribute coronary drug, Nitrostat, in China. This followed an earlier agreement with Pfizer for the distribution of 2 other drugs—Fragmin and Sermion.

The IPO will also help fund new logistics warehouses and depots and accelerate in-house R&D.

The planned IPO in Hong Kong, rather than mainland China is due to the Chinese authorities four-month block on IPOs on domestic exchanges after markets crashed and a slow start to 2016.

Pharma Investment Boosts for Malaysia

India's Biocon says its $250 million facility for insulin manufacture in Malaysia will soon be ready for commercial production.

Biocon Chair Kiran Mazumdar-Shaw says the plant will start making Biocon's insulin and insulin analogs for the local market and then move into producing product for export.

"Our facility in Malaysia will be commercialized in the H2 of the current fiscal," Mazumdar-Shaw said.

Biocon says the plant in Johor which employs 400 staff and represents the largest foreign investment made in Malaysia's biotech sector to date. It also is Biocon's first overseas biopharma manufacturing and research facility.

Biocon launched the project in 2010. Mazumdar-Shaw said at the time that she took the project to Malaysia because the company couldn't be certain of having the power and water needs of a new plant met in India.

Meanwhile, Roche Holding has announced that it is planning to invest 110 MYR ($26 million) in a newly opened service center in Malaysia over the next two years.

Roche will expand its services in finance, procurement and IT for its regional offices through the shared service center. The company has a presence in 15 countries including Australia, China, Hong Kong, India, Philippines and Vietnam. It has another five shared service centers in Europe and the Americas.

Vaccine Sales Drive GSK's Q3 Growth

GlaxoSmithKline has reported quarterly vaccine sales at £1.6 billion.

The vaccine's success stemmed from a strong quarter for flu and meningitis vaccines meningitis vaccine Bexsero more than doubled sales to £133 million over last year's third quarter, while GSK's flu vaccines grew revenue by 60% to £325 million.

Bexsero continues to gain market share and to grow the overall market, according to GSK. GSK's volume for the vaccine is approaching 10 million annual doses, up from 2.5 million a few years ago. So far, the U.K., Spain and Italy have been key markets for the vaccine.

Overall, vaccines' performance beat growth in pharma and consumer health sales by 6% and 5% respectively. The results are in line with Q2 earnings, when vaccines posted 11% growth and also outperformed other business units. Industry forecasts suggest that GSK's focus on vaccines will move it to industry sales leader by 2022 ahead of Sanofi, Pfizer and Merck. This may well be achieved following its FDA filing this month for shingles vaccine Shingrix.

Drug Price Hikes at U.S. Hospitals

A report by The American Hospital Association, says drug price hikes are "random, inconsistent and unpredictable," making it problematic for hospitals to manage their budgets.

Of the drug group examined, Valeant's Isuprel and Nitropress were credited with the highest spending, running at $86 million and $95 million, respectively, at the 2,100 hospitals included in the analysis. Over the period, the drugs - which Valeant had promised to discount - saw respective price increases of 480% and 672% from 2013 to 2015.

Valeant maintains that it's offering discounts, but in the low double digits after triple-digit hikes.

While its overall spending was low, Turing's Daraprim, saw the biggest price jump at 3,695% over the period.

The study incorporated data from 712 community hospitals, with purchasing groups adding data from another 1,400. Of the hospitals surveyed, 90% said price increases were having a "moderate to severe" impact on their budgeting.

The report comes amid a period of intense scrutiny on the pharma industry with Sen. Bernie Sanders and Rep. Elijah Cummings being two outspoken critics

Product & Innovation

Sun Pharma to Develop Dengue Vaccine

Sun Pharma and the International Centre for Genetic Engineering and Biotechnology (ICGEB) has entered into an exclusive agreement to develop a dengue fever vaccine for the rights to commercialize any resulting vaccine across India, Emerging Markets, Western Europe, Japan and the US.

GSK Announces FDA Filing for Shingles Vaccine

GlaxoSmithKline has submitted a Biologics License Application (BLA) for its candidate shingles vaccine, ShingrixTM, to the United States Food and Drug Administration (FDA).

Analysts believe it could generate more than $1 billion in revenues by 2021 and pitch itself against Merck's shingles vaccine, Zostavax which delivered $749 million in sales. Zostavax first won FDA approval in 2006.

Regulatory submissions in the European Union and Canada are on track for 2016 and planned for Japan in 2017. GSK's shingles candidate vaccine is not currently approved for use anywhere in the world.

Philips Adds Cardiac Imaging to Smartphone Ultrasound Device

The FDA has cleared Philips' cardiac transducer for use with Lumify, the company's smart-device diagnostic ultrasound. The new add-on brings cardiac imaging to the portable diagnostic.

Launched last year, Lumify consists of an app and two transducers for use with an Android smartphone, as well as access to an online portal and Philips support. The app connects to the cloud, where clinicians may access data and images.

The new cardiac transducer weighs less than a smartphone and joins the existing two transducers for use in emergency care, critical care and ambulances. Lumify's low cost and portability allows doctors in emergency situations to triage patients without needing to locate and procure an ultrasound unit.

Lumify was launched on a $199 monthly subscription model but is now also available to outright purchase.

Regulatory & Compliance

NICE Rejects Bristol-Myers' Opdivo Drug Cost

Bristol-Myers Squibb (BMS) has received downbeat news in its efforts to grow lung cancer sales in the UK.

The UK's cost watchdog NICE has turned down Bristol-Myers Squibb's cancer drug – Opdivo – claiming that it is not cost effective. However, NICE has told the company that it should seek approval through the country's Cancer Drugs Fund

A BMS statement said: NICE has said it would consider funding Opdivo through its Cancer Drugs Fund, however, it will apply restrictions that could deny treatment for up to two thirds of patients, which is inconsistent with the clinical evidence.

According to NICE calculations, Opdivo would cost between £73,500 and £150,000 per quality of life year (QALY) which the watchdog said was well beyond its cost boundaries for coverage.

BMS did offer a cost-sharing deal whereby the UK's National Health Service would pay for 26 weeks of treatment with the next 26 weeks, if needed, covered by the company.

NICE last week took a similar position on Opdivo's main competitor, Merck's Keytruda, saying it also was too expensive. But NICE didn't suggest that Merck go the cancer fund route for Keytruda.

The news knocked nearly 30% off the company's market cap with shares trading around $50, compared to $75.32 before the NICE announcement.

China Disputes Claim that 83% of Chinese Trials were Faked

China's China Food and Drug Administration (CFDA) regulatory authority is disputing reports that 83% of trials have had their results fabricated.

Last year, CFDA ordered companies behind 1,622 regulatory applications for new drugs-mainly generics- -to carry out "self-examination on the authenticity, integrity and compliance of clinical trial data."

In June, reports showed that companies had pulled 1,193 applications, which led to "reports in some media that '80% of China's clinical trial data are fraudulent'," according to a CFDA official, who insisted that those assertions "are not fact-based."

For instance, some studies may not have complied with Good Clinical Practice (GCP), while others could have had incomplete data or failed to "demonstrate the safety and effectiveness for the drug in application," the statement said.

Report Links Antibiotic Resistance to 'Dirty' Factories

A report by campaigning organization, Changing Markets says direct sampling of water from 34 manufacturing sites in India– the world's largest maker and consumer of antibiotics - has uncovered drug-resistant bacteria.

The researchers say the testing proves pharma pollution ranks alongside excessive consumption of antibiotics in human medicine and in livestock, as a key driver for resistance.

Out of 34 Indian manufacturing sites tested, almost half (16) bore resistant strains of bacteria.

At four of sites, resistance was detected to three widely-used and important antibiotic classes—cephalosporins, carbapenems and fluoroquinolones.

"Every year, nearly 1 million people worldwide die from drug-resistant infections," says Changing Markets. That figure is projected to climb to 10 million a year by 2050, it says.

However, some pharma companies have said they will make improved efforts on antibiotic waste. Last month, 13 Pharma and contract manufacturing organizations vowed to review their manufacturing and supply chains and develop standards for cleaning up antibiotic waste discharge. The companies stepping up to take the pledge were Allergan, Cipla, DSM, Sinochem Pharmaceuticals, GlaxoSmithKline, Johnson & Johnson, Merck & Co, Pfizer Roche, Ulrike Engels-Lange, Sanofi, Shionogi and Wockhardt.

EMA to Be First Regulator to Publish Clinical Study Reports (CSRs)

The European Medicines Agency has announced it will publish clinical trial data. They will be the first global medicines regulator to proactively publish the CSRs it receives from companies applying for marketing authorization.

"Transparency on clinical data is a longstanding commitment from EMA and today, we are delivering on our promise to give access to the data on which our recommendations are based," explained EMA Executive Director Guido Rasi. "Our initiative has shaped the global debate towards more transparency. It will benefit academic research and the practice of medicine as a whole."

The charity Sense about Science which runs the AllTrials the campaign for clinical trial transparency, welcomed the announcement saying;

The 700 organizations in the AllTrials campaign have been calling for this. We all now hope that other global medicines regulators will follow the European Medicines Agency's great lead.

The EMA CSR publications may have certain data redacted where such information is deemed commercially sensitive. The EMA said that its guidance "makes clear that the vast majority of the information contained in clinical reports is not considered commercial confidential information (CCI)." But where this might be the case, companies will need to submit to EMA, a justification why and which data should be redacted.

But what has been achieved is nothing short of a major shift, in just a few years, from a paternalistic attitude from both pharma and the EMA that believed the data need only be seen by these two groups, to a proactive stance by the regulator and even by some (though not all) in pharma to share this information more widely.

OpenTrials' Launches Clinical Trials Information Site

U.K.-based lobby group OpenTrials has launched a Clinical Trials information website

Its aim is to collect information around trial data and then aggregating it in order to provide a comprehensive picture of the data and documents on clinical trials conducted on medicines and other treatments around the world.

The OpenTrials team are working to create what they call a "centralized home" for all clinical trials information with trial registry entries, trial documents, regulatory documents, and publications all in one place, for use by researchers, patient groups, doctors, the public and medical professionals.

OpenTrials extracts and matches data from a number of sources including PubMed, ClinicalTrials.gov, and Drugs@FDA, as well as the EU Clinical Trials Register, the UK's Health Research Authority, and the World Health Organization's International Clinical Trials Registry Platform.

Pfizer's Lyrica Patent Appeal Fails in U.K.

England's Court of Appeal has upheld a ruling down key on patent claims on anti-epilectic drug, Lyrica and has cleared Actavis' generic of infringing it.

The patent at issue covered Lyrica's use as a pain treatment. The patent on the active ingredient - pregabalin - had already expired but Lyrica today is more for pain management than for its original use as a seizure drug.

Actavis launched a competing generic in the U.K. aimed at the epilepsy market, but Pfizer contested, saying the generic would encroach on the patented pain use. Pfizer sued for patent infringement.

Pfizer sued for patent infringement. A lower U.K. court ruled in favor of Actavis but Pfizer appealed. However, the Court of Appeal upheld the initial ruling. The company may now take the issue to the U.K. Supreme Court.

Outside the patent suit, Pfizer has sought to protect Lyrica from competition involving a battle with England's National Health Service, a strongly worded letter to NHS doctors and pharmacists, and a court order forcing the NHS to instruct doctors not to prescribe generic pregabalin to patients for pain.

After its acquisition of Actavis, Allergan's generics unit, Teva now owns the U.K. business that launched that Lyrica generic although Teva since sold the division to Indian pharma company, Intas for £600M, earlier this month.

The report comes amid a period of intense scrutiny on the pharma industry with Sen. Bernie Sanders and Rep. Elijah Cummings being two outspoken critics

Mylan Agrees $465M EpiPen Deal with Justice Department

Mylan has agreed to pay $465 million to resolve allegations that it overcharged Medicaid for EpiPen.

The deal rose Mylan shares up 10% as analysts estimated the liability to be far more than $465 million settlement.

However, the matter might not yet be entirely closed for Mylan. Rep. Elijah Cummings, ranking member of the House Committee on Oversight and Government Reform, said, "With investigations now being initiated by Congress and others, this may be the beginning of Mylan's problems - not the end."

The DOJ deal follows months of controversy over EpiPen price increases, and two weeks of close scrutiny on Mylan's rebates to Medicaid.

Painkiller Manufacturers Face Challenge on Addiction Risks

With addiction to painkillers on the rise in the U.S, New York's Broome County says it is considering doing what Illinois and New Hampshire states have done to date, namely, to sue painkiller manufacturers for misleading the public about associated addiction risks.

Earlier this month, Illinois filed suit against Phoenix-based Insys Therapeutics, accusing the company of targeting doctors, who then prescribed high volumes of an opioid nasal spray to patients who didn't qualify for the medicine. The drug, Subsys, is approved only to treat cancer pain, yet it was used for patients with other ailments.

Purdue, Allergan and Johnson & Johnson have also been sued by the city of Chicago, which accuses them of contributing to a dramatic rise in opioid addiction in the city. Chicago is seeking to recover some of the costs of dealing with the epidemic.

People News

Concordia Announces CEO Transition Plan

Concordia International Corp has announced that Mark L. Thompson will step down as CEO, following the appointment of a successor. Mr. Thompson will also step down from the Board of Directors, where he serves as Chairman, when a successor has been appointed. A search process for a new CEO is underway.