The Veeda Newsletter

April 2017

Industry growth drivers-I

Pharma Profits Continue to Dwarf R&D Spending as Pressure Mounts

With the repeal of Obamacare on life support, the furor over rising prescription drug prices and President Donald Trump's support for the cause could end up filling the vacant crossroads where bipartisanship meets change.

On Monday, Public Citizen released a new report [Editor's note: This report has since been retracted by Public Citizen due to methodological issues] trying to dispel the pharmaceutical industry's allegations that high drug prices are unavoidable because of hefty research and development (R&D) expenses to bring new medicines to market. That report plays directly into comments made last week by Trump when he met with members of the Congressional Black Caucus and reiterated his concerns about how expensive medicines are in the US when compared to other countries
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Analysts unpack CRO market Expectations

A CRO market report from ISR projects increasing outsourcing, though analysts remain less optimistic moving into 2017. "Overall, the health of the CRO looks good out to 2021 based on increased outsourcing and strong R&D spending fundamentals," Andrew Schafer, President, Industry Standard Research, told Outsourcing Pharma.com, who said that many factors that can influence the R&D budgets of organizations engaged in clinical development activities."For example, mergers at top pharma companies can sometimes slow R&D spending, VC investment levels into emerging companies can swing up and down, and new drug discovery techniques or scientific breakthroughs (or breakdowns) can influence overall spending levels," he explained. Overall, ISR's recent report shows an annual growth in the ~7% range through 2021.
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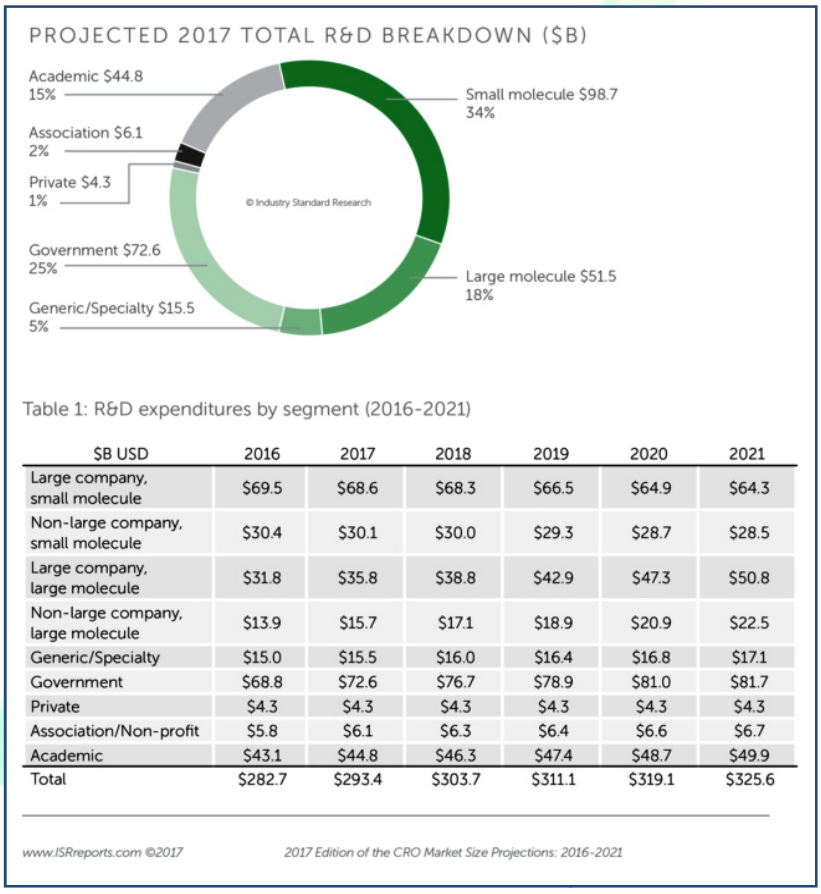

Table 1: R&D expenditures by segment (2016-2021)

$B USD	2016	2017	2018	2019	2020	2021
Large company, small molecule	$69.5	$68.6	$68.3	$66.5	$64.9	$64.3
Non-large company, small molecule	$30.4	$30.1	$30.0	$29.3	$28.7	$28.5
Large company, large molecule	$31.8	$35.8	$38.8	$42.9	$47.3	$50.8
Non-large company, large molecule	$13.9	$15.7	$17.1	$18.9	$20.9	$22.5
Generic/Specialty	$15.0	$15.5	$16.0	$16.4	$16.8	$17.1
Government	$68.8	$72.6	$76.7	$78.9	$81.0	$81.7
Private	$4.3	$4.3	$4.3	$4.3	$4.3	$4.3
Association/Non-profit	$5.8	$6.1	$6.3	$6.4	$6.6	$6.7
Academic	$43.1	$44.8	$46.3	$47.4	$48.7	$49.9
Total	$282.7	$293.4	$303.7	$311.1	$319.1	$325.6

www.ISRreports.com ©2017 *2017 Edition of the CRO Market Size Projections: 2016-2021*

Industry growth drivers-II
5 trends changing clinical trials
Clinical trials have become increasing costly ventures, adding to the overall cost of developing a drug and, ultimately, the price that patients pay for drugs. A 2016 estimate by the Tufts Center for the Study of Drug Development, for example, pegged average clinical trial costs across all three phases of development at roughly $340 million in out-of-pocket expenses. Big pharmas and small biotechs alike are looking for innovative ways to improve trial outcomes and, in turn, lower trial costs — this means increasing the efficiency in which they recruit patients, monitoring more closely how drugs are supplied and being more flexible about trial design.
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More than half of patients' out-of-pocket spending for brand medicines is based on full list price
More than half of commercially insured patients' out-of-pocket spending for brand medicines is based on full list prices, according to a new analysis from Amundsen Consulting, a division of Quintiles IMS. Even though rebates paid by biopharmaceutical companies can substantially reduce the prices insurers and pharmacy benefit managers (PBMs) pay for brand medicines, insurers use list prices—rather than discounted prices—to determine how much to charge patients with deductibles and coinsurance. The newly released data show cost sharing for nearly one in five brand prescriptions filled in the commercial market is based on the list price. Robust negotiations between biopharmaceutical companies and health plans result in significant rebates and discounts. According to a recent study from the Berkeley Research Group, more than a third of the list price for brand medicines is rebated back to payers and the supply chain. Private payers are also reportedly receiving rebates of between 30 percent and 55 percent for medicines to treat a number of conditions, including diabetes, asthma, high cholesterol and hepatitis C.
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The U.S. Burden of Neurological Disease is nearly $800 Billion/Year According to New American Neurological Association Study

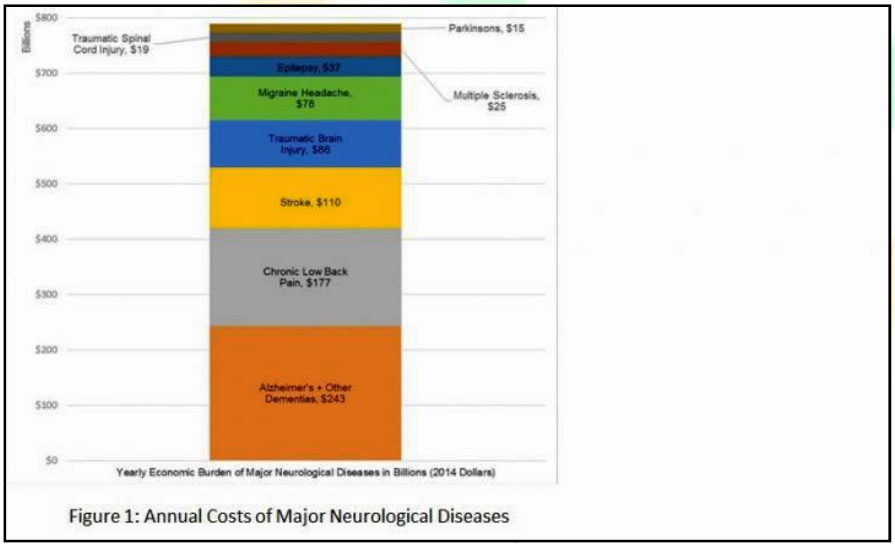

Figure 1: Annual Costs of Major Neurological Diseases

The most common neurological diseases cost the United States $789 billion in 2014, and this figure is projected to grow as the elderly population doubles between 2011 and 2050, according to a new study published in the April issue of the Annals of Neurology. The research shows the price tag of this serious, annual financial burden for the nation, and comes at a time when the new administration has proposed significant budget cuts for federally-funded research.
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Clinical Research and Clinical Trials

FDA approves first-in-human trial for neural-enabled prosthetic hand system developed at FIU

Upper extremity amputees are one step closer to successfully picking up a cookie or an egg, thanks to a new advanced prosthetic system that is designed to restore sensation.

The U.S. Food and Drug Administration (FDA) has granted an investigational device exemption for the first-in-human trial with this technology. The system was developed at Florida International University by Ranu Jung and her Adaptive Neural Systems Laboratory team.
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Galapagos Initiates Phase 1 Trial of New Therapy for CF Treatment

Galapagos initiated a Phase 1 trial to evaluate its investigational drug GLPG3067 for cystic fibrosis (CF), triggering a $7.5 million milestone payment from AbbVie, its collaboration partner.

Galapagos and AbbVie began a global collaboration in September 2013 to discover, develop and commercialize potentiator and corrector molecules for the treatment of CF.
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Sun Bio-Pharma Provides Phase 1 Trial Update; Patients Experience Early Signs of Efficacy

Sun BioPharma, Inc. a clinical stage biopharmaceutical company developing disruptive therapeutics for the treatment of pancreatic diseases, today provides top-line, interim data from the Phase 1 dose-escalation phase of its clinical study and financial results for the year ended December 31, 2016.

As previously announced on December 7, 2016, the Company completed cycle 1 dosing of patients in the fourth cohort and initiated enrollment of the fifth cohort in the dose-escalation phase of the study. The Company expects that the additional patients in the fifth cohort will complete cycle 1 dosing early in the second quarter of 2017.
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Racing in lung cancer again (or still), Merck and BMS expand Incyte combo trials

When Bristol-Myers Squibb announced Opdivo's big lung cancer trial miss last fall, it talked up Plan B: relying on Opdivo-based combos to expand in NSCLC. Since then, the company has inked or expanded a bevy of partnerships to test Opdivo cocktails in lung cancer and beyond. And so have its competitors.

For a prime example, look no further than Incyte, the Wilmington, Delaware-based biotech that's the belle of the immuno-oncology ball. On Friday, Merck & Co. said it had broadened a development deal with Incyte to test Opdivo's top rival, Keytruda, alongside Incyte's IDO1 inhibitor epacadostat. Merck would take the lead on developing the combo in a range of disease types, with first-line trials in non-small cell lung cancer, bladder cancer, kidney cancer and head and neck cancer.
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Newsmakers

Astellas Pharma has agreed to acquire privately-held Belgian drug discovery group Odega in a deal worth up to 800 million Euros.
Ogeda is a clinical-stage drug discovery company that discovers and develops small molecule drugs targeting G-protein coupled receptors (GPCRs). The firm's lead investigational candidate is fezolinetant, a selective NK3 receptor antagonist with positive data from a Phase IIa study for the non-hormonal treatment of menopause-related vasomotor symptoms. Under the deal, Astellas will make an initial payment of 500 million euros in consideration of 100 percent of the equity in Ogeda at the closing of the transaction.
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Pharma warns new NICE rules will delay access to meds
Pharma companies are warning that changes to the way the National Institute for Health & Care Excellence (NICE) and NHS England (NHSE) assess new medicines, which came into affect on April 1, will hinder patient access to the latest treatments.

In a survey of member companies of the Association of the British Pharmaceutical Industry (ABPI), 71 percent said they believe that the new system will see their companies prioritise the launch of new medicines in European countries over the UK, while 89 percent said patient access to cost-effective medicines in the UK will decrease as a result.
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Qiagen joins CANCERID, a PPP consortium aims to standardize & clinically validate blood based biomarkers

Qiagen N.V., leading global provider of sample to insight solutions, has joined CANCER-ID, a public-private consortium aiming to establish standard protocols and clinical validation for blood-based biomarkers in lung and breast cancer.

Rapid advances in the use of liquid biopsies, which enable cancer treatment and monitoring through the identification of circulating tumor cells and tumor-related nucleic acids in blood samples, have highlighted the need for standardized methods and workflows to avoid unreliable or even false analytical test results, including sequencing bias. The CANCER-ID consortium of 36 partners from 13 countries is a project of Europe's Innovative Medicines Initiative (IMI) and will conduct clinical trials using liquid biopsy methods as part of its efforts to accelerate the development of better and safer medicines for patients.
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Fact sheet

BMS' Opdivo shown to improve five-year lung cancer survival
Bristol-Myers Squibb has unveiled "unprecedented" long-term survival data for its cancer immunotherapy Opdivo, showing that nearly one in six patients with previously-treated, advanced non-small cell lung cancer (NSCLC) were still alive at five years.

In the Phase Ib single arm trial, which primarily looked at safety and tolerability across different doses, 16 percent of 129 patients reached the five-year survival mark when, typically, the five-year survival rate for advanced lung cancer is just 1 percent.
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Pharma's digital revolution turns to Austin as Merck eyes sites for 600-person IT hub
Merck & Co. is eyeing Austin, Texas, for a 600-person IT shop, one of four around the globe, as it amps up in personalized and preventative medicine.

Merck's search for a fourth site follows years of restructuring its IT operations to three hubs in the U.S., Europe and Asia. Among the locations under consideration is Austin, where Merck is asking for incentives to set up shop, according to the city.

At the proposed $28.7 million facility, Merck staffers would collect metadata and design "solution-based platforms for personalized, proactive and preventative healthcare," according to a summary (PDF) of the project. The City of Austin would throw in $856,000 in development support for the project, according to city documents.
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National agency pushback against EMA fast track continues

Germany's healthcare cost watchdog is continuing to push back against the European Medicines Agency's (EMA) plans to accelerate the approval of new medicines. The German institute worries fast-track drug approvals based on limited clinical trial data or real-world evidence will become the norm—and that this will undermine attempts to gauge the true safety and efficacy of medicines.

EMA has spent the past few years developing and piloting a scheme that would allow companies to win approval in a restricted patient population on the basis of limited data, before going on to generate additional clinical real-world evidence to support wider use of the drug. The regulator rejected most applications to join the pilot scheme—bluebird bio and Immunocore were among the successful companies—but Germany's Institute for Quality and Efficiency in Health Care (IQWiG) nonetheless fears its ideas will creep into standard practice.
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Clinical research, Clinical trials and Research Grants

FDA posts briefing materials prior to Advisory Committee meeting for nonacog beta pegol, a long-acting factor IX for the treatment of haemophilia B

Novo Nordisk today announced that the US Food and Drug Administration (FDA) has published the briefing documents ahead of the Advisory Committee meeting to discuss the Biologics License Application for nonacog beta pegol, a long-acting factor IX for the treatment of haemophilia B. The meeting takes place on 4 April 2017. The briefing documents from Novo Nordisk and the FDA, which will form the basis for the Advisory Committee's discussion, provide an overview of the non-clinical and clinical data for nonacog beta pegol for the treatment of haemophilia B.
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Once-weekly Semaglutide Demonstrated Consistent Blood Glucose Reductions and Weight Loss Regardless of Background Oral Antidiabetic Treatment

Findings from a post hoc analysis of the phase 3a SUSTAIN 2-4 trials demonstrated greater mean reductions in HbA1c and body weight with once-weekly semaglutide treatment compared to sitagliptin, exenatide extended release (ER) and insulin glargine U100 in adults with type 2 diabetes, across multiple background oral antidiabetic (OAD) treatment categories. The results were presented today at the Endocrine Society's 99th Annual Meeting and Expo (ENDO 2017) in Orlando, FL, US.[1]

"Type 2 diabetes is a complex disease, and as a result many patients are not reaching their targets on current oral antidiabetic therapy," said Vanita Aroda, SUSTAIN 4 investigator and physician investigator at the MedStar Health Research Institute, Hyattsville, MD, US. "Results from this post hoc analysis show that once-weekly semaglutide consistently lowered blood glucose and weight in people with type 2 diabetes regardless of their current oral antidiabetic therapy."
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Midtown Medical Center announces diabetes drug grant from Johnson and Johnson
Midtown Medical Center is hosting a diabetes screening on Wednesday and announced its latest grant for a new diabetes drug, "Tiger Trial."

Dr. Steven Leichter with the Endocrine Consultants PC, The Center for Diabetes and Metabolism, shared the groundbreaking news that the pharmaceutical company Janssen, which is a stem of Johnson and Johnson has provided the funds for the 'Tiger Trial.'

“Sometimes it’ll make me hate that I have it or make me hate the disease sometimes I forget I have the disease and live life as a child.”, says Type One Diabetic Christian Word.
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Hospital majors see National Health Policy & Mental Health Bill as paradigm shift in patient services

Indian healthcare providers from Cytecare to Fortis La Femme among others have viewed that the Union government's National Health Policy and the Mental Health Bill are paradigm shift in patient services. Cytecare is an organ-site based cancer network of hospitals. Fortis La Femme a chain of women and child medical centres along with other healthcare providers have expressed the two bills are much wanted to spur the growth of medical services. Read More

DCGI directs state drug controllers to strictly control manufacture, sale & distribution of oxytocin

The Drugs Controller General of India (DCGI) has directed the state drug controllers to maintain strict regulatory control over manufacture, sale and distribution of oxytocin and to curb its misuse by the manufacturers, especially where stoppage of production of oxytocin has been ordered for various reasons including non-compliance to GMP, GLP and GDP. The DCGI directive comes following a meeting in this regard convened by the secretary, Union Health Ministry on March 14, 2017 to take stock of the situation relating to restrict and regulate manufacturing of oxytocin and to permit its manufacturing in PSU in compliance to the judgement of the High Court of Himachal Pradesh.Read More

Six new medicines backed for EU approval

Six new medicines, including three orphan drugs for rare diseases, have been backed for European Union approval by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP). Read More

Asia Regulatory Roundup: Australia Considers Some DTC Drug Ads. Read More

FDA Unveils Regulatory Science Progress Report. The report, covering fiscal years 2015 and 2016, notes significant US Food and Drug Administration (FDA) progress in refining non-clinical and clinical tools.Read more

Priority Review Drugs Have Higher Likelihood of Getting Boxed Warning After Approval. A team of officials from the US Food and Drug Administration (FDA) say that drugs approved following a priority review are three-and-a-half times more likely to receive a boxed warning after entering the market. Read More

Upcoming Conferences and Events

Veeda Clinical Research will be participating in the CPhI north America Conference on May 16-18, 2017 Pennsylvania Convention Center Philadelphia, PA, USA

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