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inside

MISSING A BEAT

Dr. Harley Kurata studies the electrical processes and proteins that keep the heart beating, hoping to identify genetic mutations that cause heart disease.

NICHE-BUSTER DRUGS

The era of blockbuster drugs is drawing to a close and new drugs tailored for smaller populations and rare diseases are taking their place.

feature

FEATURE
LOOKING AHEAD

Seven trends represent the areas where biotech and pharma will be focusing their attention in 2015.

standard

EDITOR’S NOTE
NEWS
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It’s hard to believe that it’s been two years since I started working on *Bio Business*.

This magazine has taken me places I’d never thought I go, from the beaches of Carlsbad to the heights of Bogota. I’ve enjoyed every second and it’s sad to be writing my final letter for the last issue of the magazine I will work on.

But what a great issue to go out on – with cardiac disease, blockbusters and 2015 trends the main stories.

We take a look at the decline of blockbusters on page 19. Maybe it’s not so much their decline as the rise of nichebusters that’s of real interest. The industry model has basically been built on the hope of finding one or two blockbusters to drive revenue but with that model proving unsustainable, especially following the patent cliff, niche drugs are catching the eye of pharma. The move to nichebusters offers an opportunity for small and medium-sized Canadian companies as pharma will be looking to snap these businesses up to fill their pipelines.

We also have a trends story on page 8, which is always a good read. The work being done in agriculture is particularly interesting.

Cardiac disease has so many tentacles reaching so far that one story can’t possibly do this area any justice. That being said, our story focuses on some very interesting work being done by a lab in B.C. and a Toronto-based company hoping to change the way cardiac disease is treated.

Enjoy!

Nicolas Heffernan
ASSOCIATE EDITOR
François Schubert, General Manager of the Research Institute-McGill University Health Centre, was elected Chair of BioTalent Canada’s Board of Directors, at the organization’s Board meeting, which took place recently in Ottawa. The organization, a non-profit human resource organization for Canada’s bio-economy, works with corporate partners and members to ensure Canada’s biotech businesses have access to the most skilled talent available. “We’re pleased to see an individual of the stature and experience of François Schubert take a leadership role in addressing the skill challenges that face Canada’s bio-economy,” said Rob Henderson, BioTalent Canada’s President and CEO. “The entire new board now reflects the new corporate membership of the organization, and the vast array of industrial sectors they represent,” he said. The organization recently adopted new bylaws which changed the focus of the organization. With 15 new corporate members and a partnership of 35 corporations, including national and provincial industry associations, BioTalent Canada can now reach into the country’s largest number of biotech businesses. “Certainly, our recent success is due not only to the confidence our members and partners have placed in us, but also the highly visible and successful programs and projects we have implemented in recent years,” said François Schubert, Board Chair. “With their support, it is the intention of the Board to continue to grow and improve in order to address the greatest challenges facing our biotech entrepreneurs: skills and access to capital,” he said.
Women are missing from biotech boardrooms says Liftstream, which provides executive recruitment services in the biotechnology sector, in its recent gender diversity report, “Diversifying the Outlook – The X&Y of Biotechnology Leadership”. The detailed analysis of women leaders in European and U.S. biotech companies covered 700 businesses, 60 C-level interviews, and included 530 survey respondents. The report outlines how the biotechnology sector is lacking female executives and board directors. Female board directors in U.S. and EU biotech account for only 9.7% and 11.2% of positions, and only 4% of company chairpersons are female. Analysis of large-cap biotech indicated better numbers of female board members (19.2%) but was lagging in terms of female executive leaders (13.9%). Unstructured hiring processes and overreliance on male-driven personal networks are identified as underlying causes that limit opportunities for women in this field. In addition, the research also examines how the sector’s reliance on venture capital financing impacts executive and board appointments, as well as the gender diversity among these groups. Suggestions to fix these limitations include how CEOs and chairpersons must lead the change toward gender diversity, how recruiters should provide greater advocacy to companies and women on leadership, and lastly how investors should apply a structured process to ensure executive appointments are optimised for diversity. Liftstream plans to work with their global network of biotechnology and life science executives to develop further initiatives all aimed at improving awareness and the representation of women leaders in the biotech sector.

Analysis of large-cap biotech indicated better numbers of female board members (19.2%) but was lagging in terms of female executive leaders (13.9%).

GLOBAL ALLIANCE FOR GENOMICS AND HEALTH MEMBERS MEET TO ADVANCE GENOMIC DATA SHARING
The Global Alliance for Genomics and Health held its second annual meeting of the year in San Diego, California. The group of more than 140 member organizations is dedicated to improving human health by maximizing the potential of genomic medicine. The event brought together more than 250 international leaders, who all collaborated on the development of solutions that accelerate the sharing of genomic and clinical data. The group’s diverse membership includes institutions in healthcare, research, disease advocacy, life sciences, and information technology that are all working together on open interfaces and projects to enable effective and responsible data sharing.

FRANCE CONTRIBUTES $772,000 TO IMPROVE INFLUENZA VACCINES
Imxio, a biopharmaceutical company specializing in vaccines, announced it has received $772,000 of funding from the French National Research Agency for the OPTIVAC project. The aim of the project is to improve the efficacy of vaccines for seasonal influenza and pandemics. A candidate vaccine will be developed comprising of a recombinant, proprietary and highly immunogenic version of the influenza virus that is set to enter clinical trials around the start of 2017. The World Health Organization estimates seasonal influenza epidemics result in three to five million serious cases per year.

GLOBAL AORTIC STENT GRAFTS MARKET TO EXCEED $1.9 BILLION BY 2020
The global aortic stent grafts market will increase in value from an estimated $1.2 billion in 2013 to more than $1.9 billion by 2020, representing a Compound Annual Growth Rate (CAGR) of 6.7%, according to research from GlobalData. The company’s latest report states that this growth, which relates to 10 major countries, namely the U.S., France, Germany, Italy, Spain, the UK, Japan, India, China, and Brazil, will occur fastest in Japan, at a CAGR of 8.8%. There will be a slower CAGR of 5.9% in the U.S.
Pharmaceutical companies will be looking to make connections with life science firms, focus will shift from care to prevention, big data will have an important impact on healthcare, and advances in genomics will benefit the agricultural industry, say the industry insiders we polled about coming trends in the biotechnology and pharmaceutical industry.

Advances in genomics and technology have provided us with more personalized data about our bodies, why we get sick and how we will react to different medications. In the pharmaceutical industry, the focus of drug development has shifted from treating common diseases that affect wide swaths of the population to rare conditions. All this is part of an increasing trend toward wellness, rather than healthcare, says Paul Drohan, President and CEO of LifeSciences BC. “Wellness is really a look at upstream measures that we can take to help people live healthier lives in general which will, over time, help with the downstream costs [of healthcare],” he says.
Here are a few trends to pay attention to in 2015:

**BUSINESS**

**Pharmaceutical R&D on the rise**
The current high rate of pharmaceutical R&D productivity will continue, predicts Bill Stamatis, head of Deloitte’s Life Sciences division. “The evidence is showing increased value in drugs that are being currently researched,” says Stamatis. According to a 2014 study put forward by EvaluatePharma, the current value of the U.S. industry’s R&D pipeline is approximately $420 billion, an increase of 46 per cent from last year, says Stamatis.

R&D is currently focused on original biologic drugs that will serve significant unmet needs in healthcare. Payers are more than willing to invest in these high-quality drugs because biologics are less likely to be toxic to humans and are harder to create biosimilars once the patent has expired.

“Finally, we’re turning the corner on R&D and it’s becoming more productive, and I expect a continuation of that productivity in 2015,” says Stamatis. “We’ll see that in the form of regulatory approvals and launches of new molecular entities.”

**More collaboration between big pharma and life science companies**
Big pharmaceutical companies are outsourcing their R&D and collaborating with small and mid-tier life science companies, says Paola Cipolla, a partner at KPMG. “We’re really seeing pharma going to the smaller researchers and saying ‘What are you guys working on?’” she says.

The cash flows of large pharmaceutical companies are declining due to the patent cliff, leading them to outsource R&D that has historically been done internally, says Cipolla. “It’s hard for a very large pharmaceutical company to go to the government and say, ‘Help me fund this research.’ But it is much easier for a life sciences company to do that,” says Cipolla. “Government funding will tend to go to life science companies who then will partner with pharmaceutical companies.”

**Shift from care to prevention**
The pharmaceutical industry will become more focused on targeted preventative therapies in 2015, Cipolla predicts. With an aging population and growing healthcare expenditure, a greater emphasis is being placed on understanding the reasons people get sick and developing ways to stop illness in its tracks.

The shift is also being driven by more informed and engaged consumers, says Cipolla, and pharmaceutical companies are taking notice. “We’re seeing the patients raising their collective power and saying, ‘what about these diseases? Or ‘what about these conditions?’” she says. “It’s a switch for the industry and it’s very promising.”
INNOVATION
Genomics and agriculture

Advances in the field of genomics are not only revolutionizing the healthcare system but the agricultural industry as well. “There are probably more than 50 crop species now that have been totally sequenced and their genomes mapped,” says Wilf Keller, President and CEO of AgWest Bio. “This opens up tremendous opportunities for using unique DNA sequences and tracking them.” The process is referred to as marker-assisted plant breeding and is similar to the use of biomarkers in pharmaceutical clinical trials. If a connection can be made between a certain sequence and disease resistance in a crop, says Keller, it is possible to transfer that sequence to other crops without a trial and error process of infecting the plants.

Another advance in genomic research that benefits the agricultural industry is RNAi or using double-stranded RNA. The RNAi approach to genetic engineering has been around for a while now, but it is now possible to produce it relatively cheaply and in larger quantities. RNAi can be designed to target certain insect pests or unwanted weeds without modifying the genetic makeup of a plant or affecting other beneficial species in the process. “It’s really using RNA to interfere with metabolic processes or living processes of a target organism,” says Keller. “You wouldn’t be introducing new DNA, you wouldn’t have to deal with the regulatory issues around, ‘is this a genetically modified plant?’”

Neuropsychopharmacogenetics

Neuropsychopharmacogenetics is the study of how drugs interact with the brain. Although cancer research has attracted a lot of funding, a lot of it is focused on studying the way in which patients with neurological conditions like Alzheimer’s, Parkinson’s, and ADHD respond to certain drugs and not to others, says Cipolla.

“The biggest grants that have been awarded [in Canada] in the last two years have been for brain science,” she says, “particularly movement disorders like Parkinson’s and brain degenerative conditions.” This trend is connected to the overall shift from treatment to prevention, as well as an aging population and a growing number of cases of the early onset of brain degenerative conditions.

R&D is currently focused on original biologic drugs that will serve significant unmet needs in healthcare. Payers are more than willing to invest in these high-quality drugs because biologics are less likely to be toxic to humans.
Data analytics
“Data analytics is going to be a big thing in the future for the industry,” says Cipolla. Big data, a term that describes the way new technology has facilitated massive amounts of data collection across a variety of disciplines, is a concept that is already bearing fruit where it has intersected with the bioscience industry.

Right now Google is collaborating with pharmaceutical giant Novartis to create a smart contact lens that will allow diabetics to monitor their blood glucose levels without constantly pricking their fingers. Meanwhile, Jawbone’s UP wristbands give the wearer the ability to monitor everything from the number of steps they’ve taken to their heart rates, and much more. The wristband can then be synced with an iPhone and the data uploaded to the cloud. All these new technologies are feeding into what is being referred to as the quantified self movement, putting important medical data into the hands of the average citizen.

Not only will that lead to more informed patients, it will lead to a more informed healthcare system with access to more specific data on population groups and medical histories.

“Right now we’re still in the data collection stage,” says Cipolla. Someday, though, all of this data will be made available, she says, and the question will be “What does it tell you and who’s going to be able to analyze it?”

Applications in agriculture
The potential benefits of data analytics can be applied to other sectors of the bioscience industry, namely agriculture. Keller paints the picture of agricultural equipment that, with the help of computer-based sensors, can plant different types of genetic seeds at different depths and positions in a field based on information about levels of moisture and the type of soil. It’s not science fiction: companies such as U.S.-based Climate Corporation are starting to develop such machines in partnership with the agricultural industry.

“It really is the convergence of IT and crop genetics and GPS and agricultural machinery, all these things coming together,” says Keller. “All of this data is collected and the machine responds to that. It would have substantial impact on managing agricultural production.”

Big data, a term that describes the way new technology has facilitated massive amounts of data collection across a variety of disciplines, is a concept that is already bearing fruit where it has intersected with the bioscience industry.
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2015

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Researchers search for ways to minimize damage with Canada’s second and third leading causes of death: heart disease and stroke

BY NICOLAS HEFFERNAN

While reading this sentence, your heart has beat about four times.

We take it for granted, but we rely on our hearts to never skip a beat. What if you couldn’t take that constant beating for granted? Some people have to worry every beat could be their last and it’s an enormous burden to live with.

Dr. Harley Kurata is working to alleviate the fear that people with ion channel diseases live with. Ion channel mutations can cause genetic cardiac diseases in children as well as chronic diseases such as hypertension, arrhythmias, cardiomyopathy and heart failure. There are at least 970 million people worldwide with heart failure – 500,000 and 50,000 diagnosed each year in Canada.

“In a cardiac ion channel disease, the risk is you have this spectre of sudden death floating over your heart every day,” says Kurata, Assistant Professor of Anesthesiology, Pharmacology and Therapeutics at the University of British Columbia and a member of the Cardiovascular Research Group. “That would mean that every beat of my heart, every day of my life I would have that floating over my head. Those events are rare. Our hearts beat for 85 years usually without a problem.”

Electrical Heart

Every time a neuron fires in the brain, a muscle contracts or the heart beats, there’s an electrical change in the cells, which is governed by ion function. Kurata’s lab is studying the electrical behaviour in the heart and the proteins that underlie that behaviour. “The reason why I’m very interested in that is those are the proteins that govern the moment
to moment events; every contraction of
the heart, every time there's a change
in the memory voltage," he says. “That's
what underlies the heartbeat, so by
studying the ion channel proteins you
can study the things that are happening
on a moment to moment basis in real-
time that are controlling the function of
the heart.”

One strand of his research is seeking
out the actual mutations that underlie
genetic forms of heart disease. Using
genetic sequencing, Kurata searches for
ion channel genes that might be linked
to the disease. To validate them he has
to rebuild the disease in a cell type:
finding the gene, he puts the protein in,
introduces the mutation and determines
whether the mutation actually changes
the function of the protein. Some do
and some don’t, but the work he’s doing
combined with the efforts of researchers
around the world will help. “That’s going
to be a big group-driven process, where
our understanding of the variability of
genetics in humans is going to increase
as more people are identified and more
mutations are identified in people,” says
Kurata.

The next stage of his work will be
using the information he gathers to
help people. “Once you recognize the
mutations that underlie disease, you’ll be
able to develop ways to treat people more
specifically,” he says. “You’ll recognize
that a specific defect is going to be better
treated by some medicines than others,
rather than someone just showing up
with heart failure and is always treated
the same way.”

Poor Interventions
In some cases, an understanding of ion
channel function and pharmacology
has led to straightforward interventions
that substantially improve quality of life.
But some drug side effects can actually
cause ion channel disease, while most
current treatment options aren’t great.
For example, with genetic inherited ion
channel disease, some people are put on
standard old school beta blocker drugs,
while others are given implantable
defibrillators. “There’s a lot of debate as
to whether they’re effective or not and
whether they actually improve quality
of life or not,” says Kurata. “Sometimes
they shock people inappropriately or
spontaneously. So you have some poor
kid with a defibrillator implanted in his
chest and suddenly he gets shocked over
and over again. You’d like to think these

“In a cardiac ion channel disease, the risk is you have this spectre of sudden
death floating over your heart every day.”
– Dr. Harley Kurata, Assistant Professor of Anesthesiology, Pharmacology and
Therapeutics at the University of British Columbia

RIC to the Rescue
While researchers around the world
look for new insights into ion channel
diseases, a Canadian company has
a device that can help patients now.
CellAegis Devices Inc., a Toronto-based
company, has a device that can save the
heart of a patient that suffers a heart
attack, heart failure or other heart-
related events.

Myocardial ischemia occurs when
blood flow to the heart muscle is
decreased by a partial or complete
blockage of the heart’s arteries. The
decrease in blood flow reduces oxygen
supply to the heart which can damage
the heart muscle, reducing its ability to
pump efficiently. But CellAegis’ autoRIC
device, which is used in addition to
standard of care, has the potential to
revolutionize the way patients are
treated. By delivering remote ischemic
conditioning (RIC) to patients shortly after a heart event, the device activates the body’s self-defence mechanism reducing damage to organs by 40 to 60 per cent. “There’s literally nothing you can do in clinical science that will afford you that much protection. There’s nothing,” says CEO Rocky Ganske. “On some level it almost seems too good to be true but at the same time that data has been repeated and repeated and repeated in multiple trials around the world in different locations, and the data is always the same.”

The device is attached to a patient’s limb after they’ve had a cardiac event. The device is automated to give the patient four cycles of remote ischemic conditioning by occluding the limb for periods of ischemia followed by periods of reperfusion.

CellAegis was formed on the back of the intellectual property that The Hospital for Sick Children discovered. The company’s IP portfolio has been built up to the point where if a device is automated for the purposes of RIC that delivers more than one cycle of ischemia for more than one minute, CellAegis owns it. “We have a very extensive IP portfolio that we’ve gone ahead and built upon, 14 issued patents and we have 75 pending patents with patents around the world [in] Europe, Asia, U.S.,” says Ganske. “We have a very strong position.”

The autoRIC is approved in Europe and in Canada in ambulances, hospitals and the home, and is in the process of FDA approval to sell in the United States. “The health groups in Europe, especially, knowing there’s this cliff of cardiovascular disease and cost to the health system, are investing heavily in remote ischemic conditioning as a solution to the cliff of rising cardiovascular disease costs,” says Ganske. There is about $20-million-worth of third-party trials in heart attack, heart failure and trauma patients, using CellAegis’ device in Europe. “They’re all devices that will change the standard,” says Ganske. “The great thing for CellAegis is someone else is paying for all these trials and they’re using our device. We are really the only go-to folks.”

The device can help healthcare systems around the world. Heart disease and stroke costs the Canadian economy more than $20.9 billion every year in physician services, hospital costs, lost wages and decreased productivity. “The data shows you can reduce readmits by as much as 35 per cent,” says Ganske. “If you look at the benefit to the healthcare system alone, the additional capacity that the healthcare system gets just simply by delivering remote ischemic conditioning to those patients, it’s huge.”

While the device has enormous potential in the acute care (hospital and pre-hospital) market at $2 billion, the $4- to 6-billion chronic market (heart failure, stroke, home and public settings) looks even more lucrative. “This is a huge market and we are excited about being the guys that have a very unique position in this space on a therapy that’s saving a lot of lives and helping people live longer and better,” says Ganske. The current device is designed for the acute space. There are devices in about 350 ambulance and air ambulances that are used, mostly in Europe. “The device that we bring to the market for chronic use would be different than the device we have today,” says Ganske. “As soon as the data proves itself out we’ll move forward with the launch of chronic device.”

With the potential the device has, Ganske sees a big shift in the future of cardiovascular treatment. “In the future it’s unlikely that anyone undergoing any cardiovascular procedure that wouldn’t get this treatment prior to that procedure,” says Ganske. “I also see a RIC-type device hanging beside every AED that’s out there in the public space and every first responder, not only ambulance, but even police with these in their trunk to support what we suspect will be very positive outcomes in trauma.

“It’s strictly a game changer in the aspect that other than stents, there has never been any one technology that has delivered such a magnitude of positive clinical benefit. As much as we’ve done in cardiology – we being the medical community – to improve patient outcomes, to be able to achieve a 40 to 60 per cent incremental shift in myocardial loss is huge.”

Small Victories

While the autoRIC will have a huge impact on patients, Kurata is still waiting for a breakthrough with ion channel disease. He doesn’t think it will happen imminently. “It’s a difficult problem because you’re treating rare events,” says Kurata. “I think breakthroughs are going to be more and more rare. The big breakthrough now is going to be in recognizing that there’s not one big disease anymore.”

It’s a dramatic shift in thought process. “The reality is it’s not going to work for everybody,” he says. “The big breakthroughs now are going to be smaller, recognizing that heart failure is actually 20 different diseases and so figuring out one of those things is not going to be perceived as big of a breakthrough as figuring out what heart failure was 50 years ago. The big breakthrough is recognizing the variability and being able to develop things that are a lot more tailored and a lot more specific that inherently will affect less people but be more effective.”

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It appears blockbuster drugs may be going the way of the video rental store. We are living in an era between therapeutic drug revolutions, says Steve Morgan, Director of the Centre for Health Services and Policy Research (CHSPR). “The blockbuster era has dwindled, at least the primary care blockbuster era. The niche-buster is on the rise and there have been some great successes, but there are firms who are feeling the squeeze, who have not yet rode the wave of the new era,” he says.

As a number of patents for major pharmaceuticals expire, the market is becoming flooded with generics. Pharmaceutical companies, faced with this loss of capital, are looking to move toward targeted drug therapies with more definable outcomes.

“[Pharmaceutical companies] are moving in this direction rather rapidly because they have to,” says Paul Drohan, President and CEO of LifeSciences BC. A shift in focus from the oversaturated primary care pharmaceuticals to drug therapies that treat less common disease means that companies are looking to smaller life science firms and universities, traditionally centres for innovation, for the next big breakthrough.
Blockbuster Golden Era

The post-war era was a great time for the healthcare system and pharmaceutical industry, Morgan says. Enormous amounts of drug development occurred from the late 1970s to the 1990s. "Scientists were targeting small molecule pharmaceuticals to interact with known receptors in the body," says Morgan. Out of this era of rational drug development came many treatments for a host of conditions that affect large populations – conditions like hypertension, high cholesterol, depression and anxiety. But in the aftermath of that golden age, “most of the low-hanging scientific fruit had been picked,” says Morgan. Drug development began to slow down and with most of the contender molecules already in use, patents started to expire. The patent cliff has brought on a massive generization of primary care pharmaceuticals. The emergence of biologics that are harder to copy once their patents expire and have an easier time gaining approval has been the final nail in the coffin of the blockbuster era.

“There’s not a huge incentive any longer to come into those therapeutic marketplaces with a new drug because you would have to be dramatically better than your competition and you’ve got lots of it,” Morgan says.

While big pharma is beginning to see the value of niche drugs, smaller companies with niche and orphan drug treatments already in their pipelines have become more numerous. “It’s very hard to get a product approved right now,” says Henri Knafo, Medical Director at ERFA Canada 2012, which offers a range of products in various therapeutic classes such as oncology, cardiovascular and antibiotics. It’s much easier to get approval for a drug with a specific indication and which treats a condition that has no other treatment, adds Knafo.

ERFA is committed to keeping niche drugs that have been discontinued by major pharmaceutical companies on the market. When the pharmaceutical company was founded 15 years ago, it took over some niche drugs from Pfizer that the company wasn’t making money on, says Knafo. ERFA is now able to offer a variety of niche and orphan drugs – such as Thyroid, one of a few treatments for hypothyroidism available in Canada, and Amsacrine, a last-resort treatment for leukemia – in a market with very little competition and is therefore able to charge more as well.

The pharmaceutical industry may someday resemble the IT industry, with smaller companies moving in to address specific needs of the population, says Paul Drohan, President and CEO of LifeSciences BC. “The problem that is always going to be the case and will never go away is capital, and that’s the biggest hurdle companies have to overcome once they have a proof-of-principle or proof-of-concept product that is going to work,” he says.

In the U.S., the Orphan Drug Act provides an incentive to companies looking to drug treatments for rare diseases. In Canada, no such legislation exists but that could soon change.

“Here in Canada we don’t have a formalized framework yet for rare disease,” says George Wyatt, Managing Director and founder of Wyatt Health Management, a pharmaceutical reimbursement consulting firm that works with biotech and pharmaceutical companies, as well as patient advocacy groups, disease associations and policy makers. That is likely to change some time in the next several months when Health Canada approves an orphan drug regulatory framework, Wyatt says. The next challenge will be to determine pricing and reimbursement for orphan drugs. "There’s a lot of uncertainty from payers," he says, "They’re not sure what they’re buying in terms of value for money. There is political pressure to cover drugs for rare conditions. It’s very, very challenging.”

In some ways, niche drugs have already become the new blockbuster drugs. Take Sovaldi, for example. What started as a niche drug designed to treat the Hepatitis C virus, which affects an estimated 250,000 Canadians, has become one of the best-selling drugs of its time. Sovaldi has a high price tag – $1,000 (U.S.) per pill – but it has a high cure rate and minimal side effects. It achieved $8.4 billion (U.S.) in sales when it launched in December 2014. “There’s no drug that has achieved the sales as quickly as Sovaldi has,” says Morgan. “If it keeps on pace, it will surpass Lipitor in terms of the scale of single product sales.”

Despite the successes some smaller companies are finding in the niche drug market, many may quite happily find themselves being acquired by larger multinationals, Morgan says. U.S. biotech giant Gilead, which paid billions to acquire Sovaldi’s developer Pharmasset in 2011 and is now reaping billions in return, established itself as a business enterprise that acquires drugs late in the development stage.

“The discovery model of big pharma has changed,” says Drohan. “Before, everything was done in-house and now..."
they’ve recognized the fact that there’s much innovation both at academic centres but also at small or medium-sized enterprise, and to go and actually acquire innovation as well.” R&D takes place at smaller companies with specific focus, and when big pharma swoops down to swallow them up, they take over the business, the production and distribution, which they have the capital to handle.

“The firms that are selling the technologies to the new giants of this era, they’ll do well,” Morgan says. “If they’ve got a successful product on their hands, they’re going to get paid handsomely for it. But the marketing, the price points, the negotiations with regulators and payers, the business side of product launches and product sales may actually still favour larger players.”

It’s not just small and medium companies that are recognizing the value of orphan drugs, but big pharma is starting to realize that there is profit to be had with niche-busters. They are cheaper to produce and quicker to market, and they tend to be more effective because they are targeted. “Outcomes are becoming so important for payers,” says Drohan. “It’s really putting an onus on innovators to really examine what specific populations products are going to address.”

**FINDING A HOME FOR ORPHAN DRUGS**

To date, Canada has no comparable legislation to the Orphan Drug Act in the U.S., but that may soon change. Health Canada is currently reviewing an Orphan Drug Regulatory Framework that will allow drug companies to bring orphan drug treatments to market in Canada at the same time as in the U.S. and Europe and participate in international clinical trials.

The U.S. Orphan Drug Act was passed in 1983 and states that “there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs.”

According to the act, a disease or condition is considered rare if it affects less than 200,000 people in the U.S. or if it affects more than 200,000 people but a treatment is not likely to be made available as it would not make enough profit to justify the cost of development. The act offers grants and tax incentives to manufacturers of orphan drugs to offset the cost of clinical testing and development, as well as seven-year market exclusivity, assistance in developing research protocols, and expedited review for market approval (from the Canadian Organization for Rare Disorders).

In Canada, greater information sharing is the focus of the orphan drug framework Health Canada is currently hammering out. According to the Health Canada website, the proposed framework won’t make any changes to the evidentiary requirements for clinical trials, but it will look at evaluating the performance of a drug after it is approved.

Traditional statistical methods used in other drug trials don’t necessarily work for orphan drugs because their sample sizes are smaller, says George Wyatt of Wyatt Health Management. He thinks the new framework will see a relaxation in those requirements to allow for smaller trials.

“Health Canada is looking at more of a lifecycle approach for drugs,” Wyatt says. “In other words, they’ll be requesting additional data after the drug is approved. There’s more of sense of trying to understand how the drug behaves over time, versus ‘approved and done.’”

“The only thing that’s really going to take an orphan drug off the market is if the adverse events start piling up and Health Canada starts asking questions,” he says.

The proposed framework has passed the House of Commons and is headed to the Senate for approval, Wyatt says. “We’re getting very close to final approval of this particular legislative process” he says. “However, there is an election on the horizon and this type of legislation has died on the order paper before. We’re hoping that does not happen.”
This year marks the 40th anniversary of a famous archeological discovery. On November 24, 1974, in Ethiopia, the bones of Lucy were uncovered outside of the small village, Hadar. Lucy is a three-million-year-old female Australopithecus, an upright walking hominin and one of our extinct ancestors. In total, 40 per cent of her skeleton was pieced back together. Lucy was a missing link in human evolution, making her skeleton a gold mine of information to paleoanthropologists at the time. Her remains gave additional insight into early human origins, and why our distant relatives adapted the ability to walk upright.
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