Baricitinib will be the most commercially successful JAK inhibitor.

Datamonitor Healthcare forecasts baricitinib (Eli Lilly/Incyte) to be the most commercially successful JAK inhibitor in RA.

From 2017, Datamonitor Healthcare forecasts the launch of several JAK inhibitors, namely baricitinib, upadacitinib (AbbVie), and ruxolitinib (Galapagos/Gilead). In addition, Pfizer’s Xeljanz (tofacitinib), which is currently marketed for RA in the US and Japan, is anticipated to launch in the five major EU markets over the forecast period, having previously failed to receive European Medicines Agency approval in 2013 (European Commission, 2013).

The information, data, and estimates in this publication have been obtained from sources believed to be reliable. Every reasonable effort has been made to verify their accuracy. Information contained in this publication is very time-sensitive. Please note the publication date.
EXECUTIVE SUMMARY ......................................................... ES-1
i. Report overview ......................................................... ES-1
ii. Diabetes prevalence .................................................. ES-1
iii. Global diabetes management devices market .................. ES-2
    a. Selected market drivers and limiters .......................... ES-6
b. Blood glucose monitoring devices segment .................... ES-7
c. Insulin pump systems segment .................................. ES-7
d. Technology trends .................................................. ES-7
e. Market leaders ....................................................... ES-8
f. Competitive strategies .............................................. ES-8
g. Emerging competition/startups .................................. ES-10
iv. Methodology ........................................................... ES-11

Exhibit ES-1: Diabetes management devices market forecast, by segment, 2015-20 .................................................. ES-3
Exhibit ES-2: Diabetes management devices market forecast, by region, 2015-20 .................................................. ES-4
Exhibit ES-3: Diabetes management devices market, estimated share by region, 2015 .................................................. ES-5

1. OVERVIEW OF DIABETES .................................................. 1-1
1.1 Overview of Diabetes ............................................... 1-1
    1.1.1 Symptoms ...................................................... 1-2
    1.1.2 Complications ................................................ 1-3
    1.1.3 Diagnosis and treatment/prevention ...................... 1-4
        1.1.3.1 The importance of maintaining glucose control .1-4
        1.1.3.2 Limitations of self-monitoring blood glucose ...... 1-5
        1.1.3.3 Insulin and usage of insulin pumps ............... 1-6
1.2 Cost of Diabetes ...................................................... 1-7
1.3 Diabetes Prevalence .................................................. 1-7
    1.3.1 Diabetes forecast for the US, 5EU, and Japan .......... 1-7
        1.3.1.1 Type 1 diabetes forecast .............................. 1-9
        1.3.1.2 Type 2 diabetes forecast .............................. 1-9
    1.3.2 Prediabetes in the US ....................................... 1-12
1.4 New Diabetes Device Technologies, Brief Overview ........ 1-12
    1.4.1 Continuous blood glucose monitoring and patch-based systems ........................................... 1-12
1.4.2 The world’s first external artificial pancreas device system .......................................................... 1-13
1.5 Bibliography ............................................................................................................................................. 1-15

Exhibit 1-1: Estimated diabetes prevalence, worldwide and by region, 2015 and 2040 ....................................................... 1-8
Exhibit 1-2: Type 1 diabetes prevalence across the US, Japan, and five major EU markets, by country, 2015-20 .............................................. 1-10
Exhibit 1-3: Type 2 diabetes prevalence across the US, Japan, and five major EU markets, by country, 2015-20 .............................................. 1-11
Exhibit 1-4: Diagram of an artificial pancreas system (an autonomous system for glycemic control) by the FDA ................................................................ 1-14

2. GLUCOSE MONITORING DEVICES ......................................................................................... 2-1
  2.1 Selected Blood Glucose Meters ................................................................................................. 2-1
     2.1.1 Abbott Laboratories ........................................................................................................... 2-12
     2.1.2 Ascensia Diabetes Care/Panasonic Healthcare Holdings .................................................. 2-12
     2.1.3 LifeScan/Johnson & Johnson ............................................................................................. 2-19
     2.1.4 Roche ...................................................................................................................................... 2-11
  2.2 Selected Continuous Glucose Monitoring Systems ............................................................... 2-14
     2.2.1 Abbott Laboratories ........................................................................................................... 2-15
     2.2.2 Dexcom ............................................................................................................................... 2-22
     2.2.2.1 Dexcom and Google/Verily Life Sciences ..................................................... 2-25
     2.2.3 Medtronic ............................................................................................................................. 2-26
     2.2.3.1 Medtronic/Qualcomm ............................................................................................... 2-28
     2.2.3.2 Medtronic/IBM Watson Health .................................................................................. 2-30
     2.2.4 Nemaura Medical ................................................................................................................ 2-31
     2.2.5 Senseonics/Roche ............................................................................................................... 2-32
  2.3 Bibliography ............................................................................................................................................. 2-35

Exhibit 2-1: Blood glucose monitoring brands and portfolios offered by leading competitors, 2016 ......................................................... 2-3
Exhibit 2-2: Selected new blood glucose monitoring devices, 2016 ....................................................... 2-5
Exhibit 2-3: Ascensia’s new Contour Next One and Contour Diabetes app ................................................. 2-8
Exhibit 2-4: LifeScan’s new OneTouch Verio Flex .................................................................................. 2-10
3. **INSULIN PUMPS AND EMERGING INSULIN DELIVERY DEVICES** ....... 3-1
   3.1 Selected Insulin Pumps ................................................................. 3-2
       3.1.1 Animas/Johnson & Johnson .................................................. 3-2
       3.1.2 Insulet Corporation ................................................................. 3-5
       3.1.3 Medtronic .............................................................................. 3-9
       3.1.4 Roche .................................................................................... 3-11
       3.1.5 Tandem Diabetes Care ............................................................. 3-13
   3.2 Other Insulin Delivery Devices ..................................................... 3-15
       3.2.1 Cellnovo ................................................................................ 3-15
       3.2.2 Calibra Medical/Johnson & Johnson ......................................... 3-16
       3.2.3 Valeritas ................................................................................ 3-18
   3.3 Bibliography ..................................................................................... 3-21

Exhibit 3-1: Selected new or emerging insulin pump/delivery systems, 2016 ..... 3-3
Exhibit 3-2: OneTouch Ping and Animas Vibe insulin pump systems .......... 3-6
Exhibit 3-3: Omnipod and three-step insulin delivery ................................. 3-8
Exhibit 3-4: Medtronic’s New MiniMed 630G and 530G insulin pump systems.. 3-12
Exhibit 3-5: Tandem Diabetes Care’s t:sim G4 insulin pump ........................... 3-14
Exhibit 3-6: The Cellnovo Diabetes Management System ............................. 3-17
Exhibit 3-7: The V-Go Disposable and Wearable Insulin Delivery Device ....... 3-20

4. **ARTIFICIAL PANCREAS AND EMERGING/COMPETING TECHNOLOGIES** ................................................. 4-1
   4.1 Medtronic’s Artificial Pancreas - the MiniMed 670G .......................... 4-2
   4.2 Artificial Pancreas Technology - Under Development ....................... 4-5
       4.2.1 Beta Bionics .............................................................................. 4-5
4.2.2 Bigfoot Biomedical ....................................................................................... 4-10
4.2.3 Cellnovo ........................................................................................................ 4-10
4.2.4 Insulet Corporation ......................................................................................... 4-11
4.2.5 Tandem Diabetes Care/Dexcom/TypeZero ................................................. 4-12
4.2.6 TypeZero Technologies ................................................................................ 4-13

4.3 Bibliography .................................................................................................... 4-17

Exhibit 4-1: Medtronic’s MiniMed 670G, the first FDA-approved artificial pancreas ........................................................................................................ 4-4
Exhibit 4-2: Selected emerging artificial pancreas systems and expected launch, 2018-19 ........................................................................................................... 4-6
Exhibit 4-3: TypeZero’s inControl proprietary smartphone-driven hybrid closed-loop AP algorithm and partnership collaboration ..................... 4-14
Exhibit 4-4: TypeZero’s inControl smartphone-driven artificial pancreas featuring inControl Advice .................................................................................. 4-16

5. GLOBAL DIABETES MANAGEMENT DEVICES MARKET .................... 5-1

5.1 Global Market Analysis .................................................................................. 5-1

5.1.1 Market drivers and limiters ......................................................................... 5-10
5.1.2 Market forecast: US ....................................................................................... 5-11

5.1.2.1 Reimbursement issues .............................................................................. 5-16

5.1.2.1.1 Blood glucose monitors/testing supplies ........................................... 5-16
5.1.2.1.2 Continuous glucose monitoring devices ........................................... 5-17
5.1.2.1.3 Insulin pumps ....................................................................................... 5-18

5.1.3 Market forecast: 5EU ................................................................................... 5-18
5.1.4 Market forecast: Japan .................................................................................. 5-20
5.1.5 Market forecast: rest of the world ............................................................... 5-20
5.1.6 Competitive analysis: global ....................................................................... 5-22

5.1.6.1 Global market share: diabetes management devices (total market) ....... 5-22

5.1.6.1.1 Estimated global market share: blood glucose monitoring devices .................................................. 5-24

5.1.6.1.2 Estimated global market share: insulin pump systems ...................... 5-24
From 2017, Datamonitor Healthcare forecasts the launch of several JAK inhibitors, namely baricitinib, a JAK inhibitor in RA. Datamonitor Healthcare forecasts baricitinib (Eli Lilly/Incyte) to be the most commercially successful.

Rheumatoid arthritis (RA) Forecast DMKC0133573 | Published on 22/12/2016

which is currently marketed for RA in the US and Japan, is anticipated to launch in the five major EU markets over the forecast period, having previously failed to receive European Medicines Agency approval in 2013 (European Commission, 2013).

Figure 3: Sales of Humira, Enbrel, and their biosimilar versions in the US, Japan, and five major EU markets ($m), 2016–2025

Exhibit 5

5.1.7 Detailed analysis, by competitor

5.1.7.1 Ascensia Diabetes Care (formerly Bayer Diabetes Care) .................................................. 5-33
5.1.7.1.1 Strategic growth initiatives ............. 5-33

5.1.7.2 Abbott Laboratories .............................................. 5-34
5.1.7.2.1 Strategic growth initiatives ............. 5-34

5.1.7.3 Johnson & Johnson ............................................. 5-35
5.1.7.3.1 Strategic growth initiatives ............. 5-35

5.1.7.4 Medtronic .......................................................... 5-36
5.1.7.4.1 Strategic growth initiatives ............. 5-36

5.1.7.5 Roche ............................................................... 5-37
5.1.7.5.1 FY2015 ....................................................... 5-37
5.1.7.5.2 FY2016 ....................................................... 5-38
5.1.7.5.3 Strategic growth initiatives ............. 5-38

5.1.7.6 Dexcom ........................................................... 5-39
5.1.7.6.1 FY2015 ....................................................... 5-39
5.1.7.6.2 FY2016 ....................................................... 5-39
5.1.7.6.3 Strategic growth initiatives ............. 5-40

5.1.7.7 Insulet Corporation ........................................... 5-41
5.1.7.7.1 FY2015 ....................................................... 5-41
5.1.7.7.2 FY2016 ....................................................... 5-41
5.1.7.7.3 Strategic growth initiatives ............. 5-42

5.1.7.8 Tandem Diabetes Care ....................................... 5-42

5.1.6.2 Competitive analysis: US ....................... 5-27
5.1.6.3 Competitive analysis: EU ....................... 5-29
5.1.6.4 Competitive analysis: Japan ................... 5-29
5.1.6.5 Competitive analysis: rest of the world .... 5-29

5.2 Bibliography ............................................................. 5-44

Exhibit 5-1: Diabetes management devices market forecast, by segment and region, 2015-20 ........................................................................ 5-3

Exhibit 5-2: Global diabetes management devices market, estimated share by region, 2015 ........................................................................ 5-6

Exhibit 5-3: Global diabetes management devices market, estimated share by region, 2020 ........................................................................ 5-7

Exhibit 5-4: Global diabetes management devices market, estimated share by device segment, 2015 ........................................................................ 5-8
Exhibit 5-5: Global diabetes management devices market, estimated share by device segment, 2020.................................................................5-9
Exhibit 5-6: Selected market drivers and limiters for diabetes management devices ........................................................................................................5-12
Exhibit 5-7: Diabetes management devices global market, share by supplier, 2015.................................................................................................5-23
Exhibit 5-8: Blood glucose monitoring devices global market, share by supplier, 2015.........................................................................................5-25
Exhibit 5-9: Insulin pumps global market, share by supplier, 2015..................5-26
Exhibit 5-10: Diabetes management devices US market, share by supplier, 2015..................................................................................................5-28
Exhibit 5-11: Diabetes management devices 5EU market, share by supplier, 2015.................................................................................................5-30
Exhibit 5-12: Diabetes management devices Japan market, share by supplier, 2015...............................................................................................5-31
Exhibit 5-13: Diabetes management devices RoW market, share by supplier, 2015.................................................................................................5-32

APPENDIX A: COMPANY LISTING
EXECUTIVE SUMMARY

i. Report overview

This comprehensive medical market and technology report provides an overview of medical devices (specifically, blood glucose monitoring devices and insulin pump systems, including artificial pancreas systems) used in the management of diabetes, and includes an in-depth market analysis.

The report provides the following useful information:

- diabetes overview
- key statistics on diabetes prevalence in major regions in the world
- medical device product portfolios offered by leading manufacturers
- top selling products, as well as emerging new products, including novel and potentially disruptive technologies
- in-depth market and competitive analysis

Medical devices covered in this report include:

- glucose monitoring devices (used for self-monitoring of glucose), and continuous glucose monitoring (CGM) systems (Chapter 2)
- insulin pump systems (Chapter 3)
- artificial pancreas systems (Chapter 4)

ii. Diabetes prevalence

Diabetes mellitus is a group of chronic endocrine disorders, characterized by hyperglycemia due to insufficient levels of insulin, a hormone responsible for regulating blood sugar. Diabetes occurs when the body cannot use sugars properly due to impaired insulin production or utilization. Prolonged hyperglycemia (high blood sugar) can lead to serious complications including cardiovascular disease, kidney failure, diabetic retinopathy or nephropathy, and ulcers.
Exhibit ES-2: Diabetes management devices market forecast, by region, 2015-20

Source: Meddevicetracker

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1. **OVERVIEW OF DIABETES**

According to the International Diabetes Federation (IDF), approximately 415 million (or 1 in 11) adults have diabetes, and this number is expected to rise to 642 million (or 1 in 10 adults) by 2040.

In 2015, the IDF estimates that 59.8 million people had diabetes in Europe. This number is expected to increase to 71.1 million by 2040. Europe has the highest number of children with type 1 diabetes, at approximately 140,000. According to the IDF, within this region, the UK, Russian Federation, and Germany have the highest populations of children with type 1 diabetes.

In 2015, the IDF estimates that the US had approximately 29.2 million people with diabetes. Japan had approximately 7.2 million (IDF, 2015b).

According to the Centers for Disease Control and Prevention (CDC), in adults, type 1 diabetes accounts for an estimated 5% of all diagnosed cases of diabetes (CDC, 2016). Datamonitor Healthcare estimates the number of people with type 1 diabetes worldwide at 5-10% the total diabetic population (Datamonitor Healthcare, 2017a).

**1.1 Overview of Diabetes**

Diabetes mellitus is a group of chronic endocrine disorders, characterized by hyperglycemia due to insufficient levels of insulin, a hormone responsible for regulating blood sugar. Diabetes occurs when the body cannot use sugars properly due to impaired insulin production or utilization. Prolonged hyperglycemia (high blood sugar) can lead to serious complications including cardiovascular disease, kidney failure, diabetic retinopathy or nephropathy, and ulcers.

Type 1 diabetes (previously known as insulin-dependent, juvenile, or childhood-onset) accounts for around 5-10% of the total diabetic population. The majority of cases of type 1 diabetes may be classified as type 1a, an autoimmune disease characterized by the destruction of pancreatic beta cells, with a minority of cases making up type 1b, which is described as idiopathic diabetes mellitus. In both cases, insulin therapy is necessary from disease onset and requires frequent monitoring and maintenance. The underlying cause of type 1 diabetes is not known and it is not preventable (Datamonitor Healthcare, 2017a).
In August 2016, Roche announced the launch of another new glucose meter system designed with improved accuracy - the Accu-Chek Guide - in selected countries outside the US; the company is planning initial launch in Denmark, Switzerland, and Australia in the first quarter of 2017 (Roche 2016b). The system features a new strip designed with a unique, larger, easy-edge dosing area for more accurate testing, and a spill-resistant test strip vial. The system also simplifies and improves diabetes management via remote monitoring or “telemedicine,” using wireless connectivity to the Accu-Chek Connect diabetes management mobile app. Connectivity allows better diabetes management and assessment of high-low blood glucose levels, instant alerts, and remote monitoring via a Bluetooth Low Energy cloud-based solution.

2.2 Selected Continuous Glucose Monitoring Systems

Currently primarily prescribed under the order of a physician, continuous glucose monitoring (CGM) systems measure interstitial glucose levels in real-time, 24 hours a day, to provide a more complete understanding of glucose levels and trends than traditional home-use glucose meters, which only provide a “snapshot” of glucose levels at a brief moment in time. The goal of CGMs is to improve diabetes treatment and glucose control primarily for people with type 1 diabetes (although some type 2 diabetics are also eligible who suffer from frequent hypoglycemia). CGMs require significantly fewer fingersticks, which are extremely cumbersome and somewhat painful, especially for children, and provide parents/caregivers and healthcare providers with alerts to prevent dangerous hypoglycemia. They can therefore ease parents’ worries, and help patients to better control or manage symptoms through improved diet and lifestyle decisions. CGMs provide alerts regarding high and low glucose levels, and may even give early/preventive alerts to upcoming highs/lows, as well as useful glucose trend data, and information regarding how a patient’s diet, illness, medication, and exercise impact blood sugar.

According to Dexcom, a leader in CGM technology, CGM is one of “the most significant breakthrough in diabetes management over the past four decades” (Clarke SF, et al, 2012) due to its ability to not only provide the current glucose level, but to display the direction and rate of glucose change and provide immediate alerts when glucose is too low or high. Additionally, standalone CGMs (when used alone regardless of insulin delivery method including insulin pumps) have the capability to result in significant A1C reductions.
CGMs typically include four components: a CGM monitor or insulin pump with built-in CGM capability (eg MiniMed insulin pumps have integrated CGMs); a small, waterproof transmitter that attaches to the sensor and wirelessly sends glucose data to the monitor/pump; an adhesive, replaceable/disposable sensor inserted under the skin via a needle; and an easy-to-use push button insertion device.

Unfortunately, CGMs (with the exception of Abbott’s new FreeStyle Libre Pro/Flash device) still require fingerstick calibration (eg Medtronic’s CGMs and even Dexcom’s G5 require at least one fingerstick every 12 hours) and therefore do not completely replace home self-monitoring glucose meters.

CGMs can be used by both type 1 and type 2 diabetics, although they are primarily used by type 1 diabetics due to the critical need for tight glucose control, or by users (eg children) who need to reduce A1C without increasing hypoglycemia, or who suffer from frequent lows and potentially dangerous nighttime hypoglycemia.

Leading competitors in the CGM systems segment include: Abbott Laboratories (FreeStyle Libre Pro/Flash); Dexcom (G5 Mobile); and Medtronic (iPro/Enlite sensor used with the MiniMed insulin pump, and Guardian Connect mobile CGM). However, several new competing systems are under development, from companies such as Nemaura Medical (sugarBEAT), Senseonics/Roche (Eversense), and others.

Medtronic has incorporated CGM technology into its dominant line of insulin pumps and new artificial pancreas. However, Dexcom, which leads the standalone CGM segment, is also partnering with several startups developing competing closed-loop insulin pump/artificial pancreas technologies to integrate their G5 CGM technology (see Chapter 4).

Selected companies and products are briefly profiled in the following sections, and selected new products are listed in Exhibit 2-6.

### 2.2.1 Abbott Laboratories

In September 2016, Abbott gained FDA approval for the FreeStyle Libre Pro CGM, a professional-use device that is groundbreaking in that it eliminates the need for routine fingersticks; the system also does not require fingerstick calibration due to
3. **INSULIN PUMPS AND EMERGING INSULIN DELIVERY DEVICES**

The lucrative global insulin pump market - estimated at more than $3bn in 2015 - primarily serves a type 1 diabetes population (adults and children with type 1 diabetes) in critical need of life-saving automatic insulin regulation and delivery, due to their lack of insulin because of autoimmune damage to the pancreas, but also relates to type 2 diabetes patients with poor glycemic control. For children in particular, an insulin pump, similar to a pancreas, continuously delivers insulin and replaces the need to administer painful insulin injections using syringes or pens (according to Medtronic, with a dramatic reduction in needlesticks - from three to four daily with injections, to only one every two or three days with a pump). Medtronic, a leader in insulin pumps, claims it serves more than 250,000 families with diabetic children.

The larger type 2 diabetes population is also a target of insulin pump manufacturers, as type 2 diabetics can also benefit health-wise from using insulin pumps over using traditional pens/syringes. In the large OpT2mise clinical study comparing insulin pump therapy using Medtronic's MiniMed pumps versus multiple daily injections (MDIs), patients using MiniMed pump therapy achieved a 1.1% reduction in A1C (glycated hemoglobin) compared to only a 0.4% reduction with MDIs, and twice the rate of patients in the MiniMed pump users group (or 55%) achieved an A1C below 8% compared to 28% of those on MDI (Reznik et al., 2014). A reduction in A1C can lead to a reduction in many diabetes co-morbidities, such as cardiovascular damage, nerve damage, eye damage/retinopathy, and kidney damage.

Insulin pumps are small, cellphone-sized, highly sophisticated, externally worn/wearable devices (typically worn on a belt or inside a pocket) with several components, such as a wireless remote, insulin reservoir/cartridge, infusion set (thin, flexible tube which connects the pump to the body and allows the injection of insulin using an angled insertion, featuring a discreet design, and various cannula and tubing sizes that are replaced frequently), and integrated continuous blood glucose monitor (CGM). They are designed with advanced algorithms that calculate and administer accurate basal and bolus insulin doses (an automatic constant supply of basal dose 24 hours a day and the ability to calculate bolus dose after meal intake to correct high blood sugar).
One reason for the highly lucrative market, despite lower product volume (compared to glucose meters), is the fact that expensive insulin pump systems also require the costly ancillary purchase of various pump supplies (sold separately), including disposable/consumable insulin cartridges/reservoirs; disposable infusion sets; insertion devices; diabetes management software; and other accessories. Consumables/disposable products such as cartridges and infusion sets, in particular, contribute substantial supplementary revenues to insulin pump manufacturers.

3.1 Selected Insulin Pumps
While the market is dominated by Medtronic (with its long-established MiniMed brand), a variety of insulin pump systems are available from highly competitive, leading diabetes management medical device companies, including Animas Corporation/Johnson & Johnson (OneTouch Ping and Animas Vibe); F. Hoffman-LaRoche/Roche (Accu-Chek Combo insulin pump and new Accu-Chek Insight); Insulet Corporation (Omnipod); and Tandem Diabetes Care (t:slim).

Leading companies and products are briefly profiled in the following sections, and selected new and emerging products are listed in Exhibit 3-1.

3.1.1 Animas/Johnson & Johnson
Johnson & Johnson’s Animas Corporation offers a portfolio of insulin pumps, including the OneTouch Ping and Animas Vibe System. The company’s OneTouch Ping is a two-part glucose management system that includes the OneTouch Ping Insulin Pump and a meter remote, which wirelessly communicates information between the pump and meter remote, automatically and continuously administers pre-set basal insulin, and checks blood sugar and calculates how much bolus insulin is required to deliver insulin from the pump, without requiring the user to touch the pump, from up to 10 feet away. The device allows a wide range of basal insulin dosing options, at low basal increment of 0.025 U/hr, and a highly accurate post-meal bolus calculator automatically calculates how much bolus insulin is required to cover carbohydrates (carbs) eaten, or to correct high blood glucose. Unlike other pump systems, the OneTouch Ping Meter Remote allows carb counting, storing the nutritional value of 500 foods in a CalorieKing database.
The recent development and launch of the first artificial pancreas (by Medtronic) in the US is perhaps one of most revolutionary advances in medical device history. While time will tell if it remains clinically efficacious, the next-generation insulin pump technology is expected to flourish over the next decade, helping to offset the recent slowed growth in the diabetes management devices market (eg blood glucose meters) with high single-digit growth or even double-digit growth, based on continued safety and efficacy and improvement of the lives of people with type 1 diabetes worldwide, who desire more freedom, tighter control of glucose fluctuations, fewer complications, and greater ability to live more “normal” lives.

Artificial pancreas technology was developed out of a strong need to eliminate numerous, painful and cumbersome daily fingersticks and replace traditional uncomfortable insulin delivery via needles/syringes/pens, and to automatically and continuously monitor and administer insulin as the body requires, mimicking the actions of a human pancreas in those with potentially life-threatening type 1 diabetes.

The artificial pancreas (AP) system is sometimes termed a “closed-loop” system because a computer-controlled algorithm (run on a computer, smartphone, or insulin pump) receives continuous glucose information from a continuous glucose meter (CGM), and performs mathematical calculations to send dosing instructions to the insulin pump in a closed/circular method of communication, resulting in the automatic adjustment of insulin in both directions in order to maintain optimal or target glucose levels. The goal of the next-generation AP system is to provide tighter glucose control or more accurate regulation of blood sugar levels in people with insulin-dependent type 1 diabetes, virtually eliminating hypoglycemic episodes (especially at night or during exercise) or hyperglycemic events and long-term complications to improve the patient’s health and overall well-being, and provide greater freedom from a previously worrisome and cumbersome 24/7 insulin monitoring and blood glucose monitoring routine.

This chapter provides an overview of the recently approved first AP system by Medtronic, which is expected to dominate the market due to its monopoly and the company’s expertise. However, the company will soon be facing several emerging
### Exhibit 4-2: Selected emerging artificial pancreas systems and expected launch, 2018-19

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Expected approval/features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta Bionics (in conjunction with Zealand Pharma) and Dexcom</td>
<td>iLet and Dexcom CGM</td>
<td>(Phase II study in progress; expected approval 2018/2019) The only dual-hormone (insulin/glucagon), dual-pump “bionic pancreas” system integrated into a pocket-sized wearable medical device (currently iPhone4S) with Dexcom CGM; uses Zealand Pharma’s novel liquid stable glucagon analog, ZP4207, or Lilly’s glucagon.</td>
</tr>
<tr>
<td>Bigfoot Biomedical</td>
<td>Bigfoot Type 1 Diabetes Management System (smartloop diabetes management system)</td>
<td>(Phase I trial results pending; expected approval late 2018/early 2019) A smartloop automated insulin delivery service/integrated cloud-connected diabetes management system for type 1 diabetes patients, uniquely delivered as a monthly medical device-based service; system imbeds a closed-loop control algorithm into a sensor-augmented insulin pump and interfaces with smartphone and Dexcom CGM.</td>
</tr>
</tbody>
</table>

(continued)
Exhibit 5-1: Diabetes management devices market forecast, by segment and region, 2015-20

(continued)
Exhibit 5-6: Selected market drivers and limiters for diabetes management devices

<table>
<thead>
<tr>
<th>Drivers</th>
<th>Limiters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly favorable demographics - a large aging and growing diabetes population worldwide; continued growth in the number of people with diabetes in the largest market of the US, where diabetes will remain at &quot;epidemic&quot; levels, as well as in several international markets, such as some areas of Europe (eg Germany), Asia-Pacific (eg India), Russia, and Latin America (eg Brazil).</td>
<td>Price erosion - the number one issue negatively impacting the diabetes management devices market (the glucose monitoring/self-monitoring segment) is continued price erosion stemming from significant 2013 cuts in Medicare reimbursement or changes in reimbursement policies in the US for blood glucose monitors, particularly the previously lucrative test strips, and the ongoing impact/spillover to the private insurance sector, lowering prices industry-wide; however, it is believed that price levels have bottomed out, and the market is stabilizing in 2017 and beyond.</td>
</tr>
<tr>
<td>The strong need/necessity for blood glucose monitoring systems and insulin pumps in maintaining good glucose control, preventing life-threatening hyper/hypoglycemia or other diabetes complications, and improving quality of life; strong demand for technology that lessens fingersticks using lancets, or painful insulin injections using pens/syringes.</td>
<td>In the US, ongoing uncertainty as to the future of the Affordable Care Act and the Trump Administration’s repeal and replace initiative may further impact the market (eg new cost-cutting measures for Medicare may be enacted that further negatively impact diabetes care device/consumables pricing) and manufacturers’ profitability.</td>
</tr>
<tr>
<td>Strong clinical safety and efficacy of glucose monitoring and insulin pump technologies, barring any future adverse events.</td>
<td>Economic volatility or uncertainty and consumer financial difficulties will continue to delay the purchase of costly next-generation diabetes management devices (eg CGMs) that require high patient out-of-pocket, particularly in markets/countries with low insurance coverage.</td>
</tr>
</tbody>
</table>
complementing, not replacing, self-monitoring glucose meters. Standard blood glucose monitoring devices/meters and test strips have been covered as a DME under Medicare since the 1980s. Prior to 1998, they were only covered for type 1 diabetes, but expanded to both type 1 and type 2 diabetes following the Balanced Budget Act of 1997, enacted on 1 July 1998 (CMS Ruling, 2017).

5.1.2.1.3 Insulin pumps
Similar to self-monitoring blood glucose monitoring devices, which are medically necessary for patients to monitor glucose levels for control of their diabetes, insulin pumps are covered by Medicare Part B (with 20% out-of-pocket co-insurance) as a DME that is physician-prescribed for use in the home (CMS, 2017). However, they are also widely covered by private insurance (minus possible patient deductible/co-insurance or out-of-pocket pay), benefit from higher prices and profitable components/pump supplies, and have not suffered from CMS reductions seen in the blood glucose testing segment due to a stronger medical necessity for type 1 diabetes patients.

5.1.3 Market forecast: 5EU
The market for diabetes management devices in the five major EU markets was valued at approximately $2.4bn ($2,412.3m) in 2015, or approximately 27% of the total/global market, third in size behind the US (which is estimated to have contributed more than 40% of the market) and nearly equal to the size of the market allocated to the RoW (which is valued slightly higher and also contributes an estimated 27%). Over the forecast period covered by this report, total 5EU sales are expected to increase at a CAGR of 4.5%, reaching more than $3bn ($3,005.7m) in 2020, the second highest expected growth rate following the US.

In 2015, glucose meters and CGMs are estimated to have contributed more than 73% of diabetes management device sales in the 5EU, or nearly $1.8bn ($1,768.9m), and insulin pumps represented 27% of the market, or an estimated $643.4m. However, as in the US, the insulin pump segment is expected to achieve higher growth, at a 6.2% CAGR over the forecast period, compared to a lower 3.8% CAGR for glucose meters/CGMs.
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