
1Q18-2Q18 Diabetes Technology Industry Roundup - Breakout 1H18 for CGM as sales of ~\$1.2 billion rise 60% YOY; Strong pump sales of ~\$1.3 billion rise 20% in 1H18, while BGM declines ~1% - September 20, 2018

Executive Highlights

- **CGM has had a truly breakout half-year: We estimate global sales were ~\$561 million in 1Q18 (+55% YOY) and a record-smashing ~\$652 million in 2Q18 (+64% YOY).** This marked the first-ever half-year crossing \$1 billion in CGM sales, an *acceleration* from 1H17's ~50% YOY growth, and places CGM nearly on par with the size of the global insulin pump industry (in our model). Both 1Q18 and 2Q18 saw international CGM sales *exceeding* US sales - the first time we've ever seen this in our model. We estimate international CGM sales were ~\$305 million in 1Q18 (+81% YOY) and ~\$337 million in 2Q18 (+71% YOY), propelled massively by FreeStyle Libre: we estimate Abbott provided ~75% of 1H18 CGM category growth outside the US. US CGM sales were an estimated ~\$256 million in 1Q18 (+33% YOY) and ~\$315 million in 2Q18 (+56% YOY). We estimate Dexcom provided ~44% of 1H18 CGM category growth in the US, a downtick from the 53%-73% share of growth Dexcom had in the US in in 2017 - as expected, this now reflects a far more competitive US standalone CGM market. The acceleration in CGM could mark an inflection point in the field: moving from an early adopter technology to a broader user base, especially with four excellent CGMs.
- **BGM struggles continue: Pooled global BGM-only revenue for Roche, J&J, and Abbott totaled an estimated ~\$985 million in 1Q18 (+2% YOY) and ~\$1.0 billion in 2Q18 (-4% YOY).** Both came on easy comparisons to declines of 3% and 8% in 1Q17 and 2Q17, respectively. International BGM sales totaled an estimated ~\$743 million in 1Q18 and ~\$776 million in 2Q18, rising ~6% YOY and falling ~1% YOY, respectively. The US BGM market is showing no sign of recovery, with estimated pooled sales of ~\$242 million in 1Q18 (-9% YOY) and ~\$270 million in 2Q18 (-11% YOY) - this marks seven consecutive quarters of pooled YOY declines. The one positive is arguably in the international market, which saw three consecutive quarters of positive YOY growth (3Q17-1Q18), followed by a softer 1% YOY decline in 2Q18. We estimate Roche had the strongest performance in 1H18: sales were an estimated \$439 million in [1Q18](#) (+11% YOY) and ~\$485 million in [2Q18](#) (+4% YOY).
- **Insulin pumps/delivery devices rose ~20% YOY in both 1Q18 (~\$679 million) and in 2Q18 (~\$630 million), marking three consecutive quarters of positive YOY growth for the industry.** 1Q18 was actually an industry revenue record (~\$679 million), handily surpassing the previous 4Q17 record of \$651 million. Estimated US pump revenue totaled ~\$382 million in 1Q18 (+19% YOY) and ~\$362 million in 2Q18 (+28% YOY), while estimated international pump sales hit a record ~\$298 million in 1Q18 (+21% YOY) and totaled ~\$268 million in 2Q18 (+12% YOY). With the obvious exception of Animas, we estimate every company saw growth in both 1Q18 and 2Q18. Medtronic has carried the field in 2018, with an ~70% market share by sales and supplying ~73% of 1H18 pump industry growth - its highest contribution in nearly five years! Insulet and Tandem have also seen very strong revenue growth in 1H18, though with Medtronic's gains, both companies have made smaller contributions to global pump industry growth (~14% and 9%, respectively) than we saw in 2H17.

Following the conclusion of 2Q18 earnings season, this report includes a financial roundup of the diabetes technology field - CGM, BGM, and insulin pumps and delivery devices based on ten public companies. We analyze each segment's sales performance and provide graphs with current and historical trends.

Please note that in many cases, we've made our best estimates, since a number of companies don't disclose financial information in great detail. We've made the basis of our assumptions clear in the sections below, but recognize a number of the estimates may be wrong in magnitude and direction. If you have opinions on how an estimate could be improved, please [reach out and let us know!](#) We'll return soon with a Diabetes Therapy and an Overall Industry roundup!

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BGM

Roche, J&J, and Abbott Pooled BGM Sales Total ~\$2.0 Billion in 1H18, Down ~1% YOY; Has the OUS Market Stabilized?

Insulin Pumps and Delivery Devices

1H18 Sales of ~\$1.3 billion up 20% YOY; Industry Record High in 1Q18 (~\$679 Million); Strong 1H18 for Medtronic (~72% of industry growth)

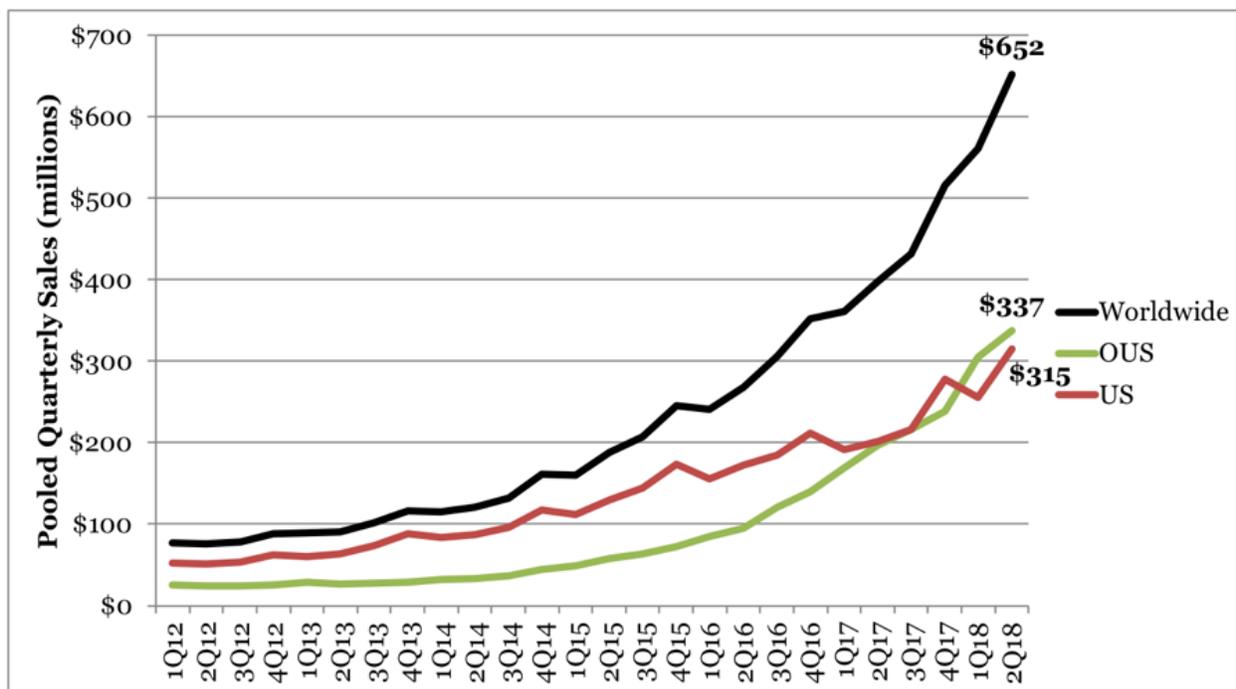
Diabetes Technology

CGM

Global CGM Sales of ~\$1.2 billion in 1H18, an Impressive ~60% YOY Rise = Faster Growth from a Higher Base; 1st Ever Half-Year Crossing \$1 Billion! Freestyle Libre (Est) Drives ~60% of CGM Category Growth

CGM Sales by Geography, Estimated (1Q12-2Q18)

Dexcom, Abbott (estimated), Medtronic (estimated), Senseonics



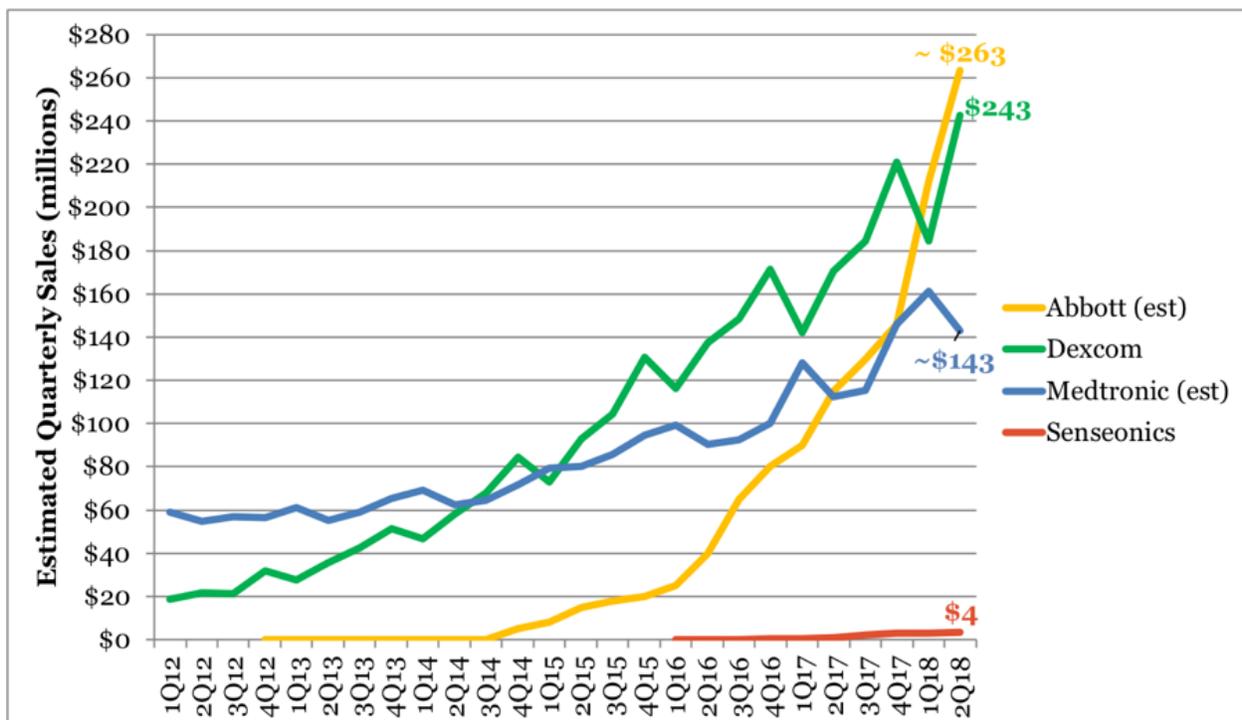
By our estimates, the worldwide CGM market grew to ~\$1.2 billion in the first half of 2018, up an impressive ~60% YOY from 1H17. This represents faster growth from a much higher base of sales - 1H17 saw sales of ~\$759 million rise ~50% YOY. We estimate global CGM sales were ~\$561 million in 1Q18 (up ~55% YOY) and a record-smashing ~\$652 million in 2Q18 (up ~64% YOY) - the latter was a milestone for the category, crossing \$600 million in quarterly sales for the first time in our CGM model. Notably, 4Q17 was the first time crossing \$500 million in quarterly sales, meaning 1H18 has been quite the half year for the category. The acceleration is a testament to what could be an inflection point in the field: CGM may finally be moving from an early adopter technology to a broader user base, especially with four excellent sensors on the market, two factory calibrated sensors, two AID systems in the US, balanced US and OUS momentum (especially OUS sales for FreeStyle Libre), and rising clinician enthusiasm. Both 1Q18 and 2Q18 saw international CGM sales *exceeding* US sales - the first time we've ever seen this (more geographic details below). Assuming seasonality, CGM is on pace to handily cross \$2.5 billion in sales for all of 2018!

- By company, we estimate Abbott has provided the majority of the CGM category's 1H18 growth: ~61% of 1Q18 growth and 58% of 2Q18 growth.** Abbott has seen remarkable expansion in its user base, which is now over 800,000 globally and makes it the #1 CGM worldwide by user base. Our model estimates Abbott has provided the largest share of CGM category growth for eight straight quarters now. Dexcom has also had a strong start to 2018, providing ~21% of 1Q18 category growth and 28% of 2Q18 growth. Finally, Medtronic drove ~17% (1Q18) and ~12% (2Q18) of the category's growth, while Senseonics has provided ~1%. Our model includes Dexcom's reported sales, our best estimates for Medtronic and Abbott's FreeStyle Libre (clarified below), and Senseonics' reported sales. This is the third roundup where we've included sales estimates for Abbott's FreeStyle Libre in the CGM category, which we pegged at roughly ~\$212 million in 1Q18 and ~\$263 million in 2Q18 - assumptions are below, and we caution these might over- or underestimate FreeStyle Libre's actual global sales. (Our CGM model shown above includes historical sales estimates back to Libre's launch in Europe in fall 2014. The BGM section further below reports our estimate for Abbott's traditional fingerstick business, subtracting out our estimate for Libre.) Meanwhile, Medtronic told us in mid-2017 that its CGM sales are now ~25% of its Diabetes sales, up from ~20% two years ago. We include a more detailed geographic and company-by-company analysis below.

- **International CGM growth continues to be a story in 1H18, following strong momentum in 2017. We estimate a record-high ~53% of CGM sales came from outside the US in 1H18 (~\$642 million),** marking two consecutive quarters where international sales were *greater than* US sales. Our model has never before seen this in the CGM category, as shown in the graph above (green line overtaking red line). That said, both US and international sales are seeing sustained category growth, as the slopes of the lines are almost identical.
 - **We estimate international CGM sales were ~\$305 million in 1Q18 (+81% YOY) and ~\$337 million in 2Q18 (+71% YOY), mostly driven by FreeStyle Libre.** CGM sales outside the US drove an impressive ~68% of 1Q18 CGM category growth, but then softened to only ~55% of the category's 2Q18 growth - the latter was the lowest seen in the past two years, reflecting very strong quarters in the US for Dexcom and Medtronic and expanding uptake for FreeStyle Libre in the US. By company, we estimate Abbott provided ~75% of 1H18 CGM category growth outside the US, on par with its 2017 performance. Dexcom supplied the second-largest share of 1H18 OUS CGM growth (~13%), followed by ~10% from Medtronic and ~2% from Senseonics. Clearly, FreeStyle Libre continues to dominate the OUS market and drive most of the category's growth; indeed, FreeStyle Libre's OUS CGM sales (estimated) of \$219 million in 2Q18 were more than quadruple Dexcom's OUS business (\$53 million) and more than triple Medtronic's estimated OUS CGM business (~\$62 million).
- **US CGM sales were an estimated ~\$256 million in 1Q18 (+33% YOY) and ~\$315 million in 2Q18 (+56% YOY).** The US provided 45% of the CGM category's growth in 2Q18, its highest point in eight quarters.
 - **US growth was led by Dexcom, but showed more balance across the companies vs. 2017.** We estimate Dexcom provided 43% of 2Q18 CGM category growth, a notable downtick from the 53%-73% share of growth Dexcom had in the US in 2017 and the 80%-97% (!) share of growth it had in the US in 2016. As expected, this now reflects a far more competitive US standalone CGM market, which in 1H18 included FreeStyle Libre real-time and Medtronic's Guardian Connect - products not available in the US this time last year. Indeed, we estimate Abbott provided a strong 39% share of US CGM category growth in 2Q18, while Medtronic contributed 18%. (Both of these are highly estimated, so we could be under- or over-reporting.) We note that Senseonics' Eversense will start to show up in 2H18 sales in the US, as the first Eversense insertions occurred in July.
 - **We expect CGM sales to accelerate significantly in the US in 2H18 for several reasons:** (i) Dexcom had minimal contribution from G6 in its already-strong [2Q18](#) (see below); (ii) Abbott [just secured FDA approval](#) for 14-day wear FreeStyle Libre real-time with a 1-hour warmup; (iii) Medtronic's Guardian Connect only [launched in mid-June](#); and (iv) Senseonics Eversense had the first insertions [in late July](#). Plus, seasonality always means 2H18 is stronger than 1H18 in the US. With all that mind, we expect a larger share of category growth from the US in 2H18, even as CGM adoption continues outside the US.

CGM Sales By Company, Estimated (1Q12-2Q18)

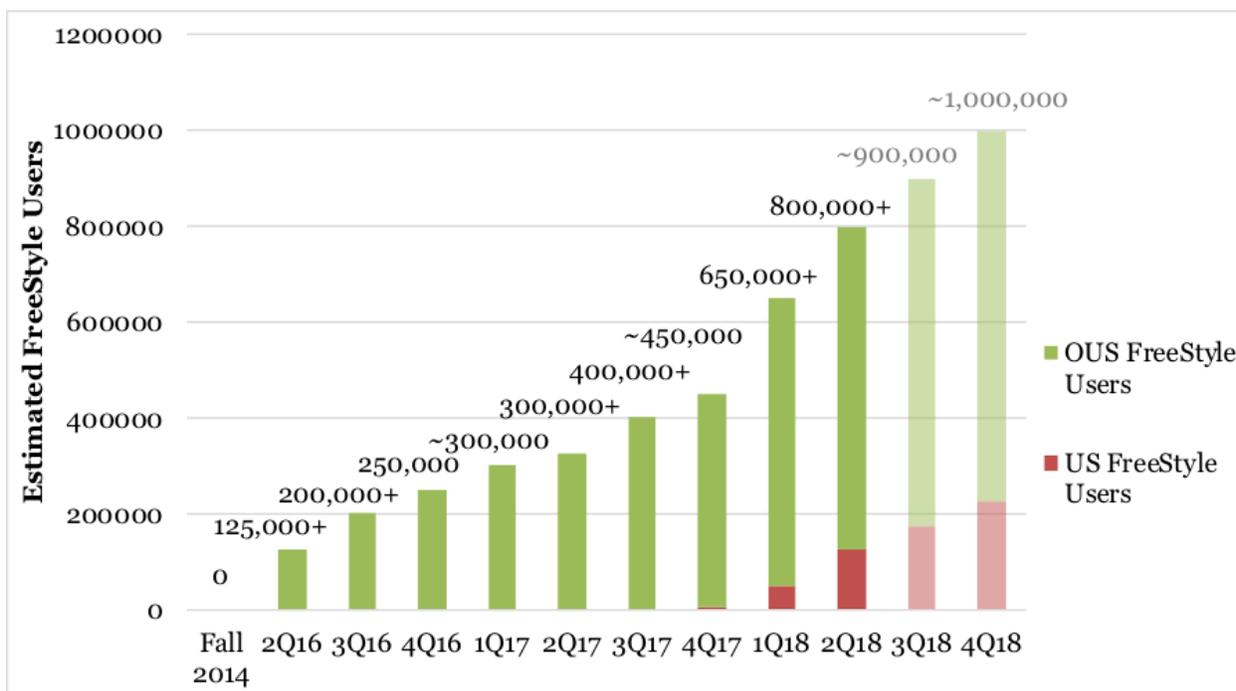
Global Sales: Abbott (estimated), Dexcom, Medtronic (estimated), Senseonics



- We estimate worldwide sales of Abbott's FreeStyle Libre were roughly ~\$212 million in 1Q18 (+116% YOY) and ~\$263 million in 2Q18 (+90% YOY) - both came on extremely difficult comparisons to estimated global sales more than doubling in 1Q17 and 2Q17. We estimate FreeStyle Libre's OUS sales were ~\$219 million (+90% YOY) with ~675,000 users in 2Q18, while US sales were ~\$45 million in 2Q18 (+100%) with an estimated ~125,000 users. These sales figures reflect our best estimates based on a number of assumptions - many of which could be incorrect. We detail our thinking and assumptions below, beginning with a graph and data table we've used to inform our model. It's been excellent to see the success of this well-priced, easy to prescribe, easy to order, factory calibrated CGM. We can't wait to see how FreeStyle Libre fares in 2H18, now that it has [14-day FDA approval](#) with a one-hour warmup in the US, and now that Dexcom's G6 is launching globally with competitive factory calibration. Plus, we look forward to updates on the FreeStyle LibreLink apps in the US and the next-gen FreeStyle Libre with continuous communication. At [FFL 2018](#), Bigfoot CEO Jeffrey Brewer said the latter is coming "sooner than people realize. On Abbott's [2Q18](#) call, CEO Miles White confirmed previous guidance for \$90-\$100 million in 2018 US FreeStyle Libre revenue. Assuming our estimates are not far off, Abbott might actually exceed \$1 billion in Libre revenue globally in 2018, along with >1 million patients - that would be something! Read [our Abbott 2Q18 report](#).**

FreeStyle Libre User Base and *Estimated* Quarterly Sensor Revenue

- In the graph below, pale colors and text represent projections based on CEO Miles White's [2Q18](#) statement that the user base will reach one million patients by the end of 2018. Estimates on the right side assume equal distribution of new users across the remaining quarters of the year and between US and OUS. Given recent patient growth of +150,000-+200,000 per quarter, Abbott seems very well positioned to exceed one million users by the end of 2018 - perhaps even in Q3.**



		1Q17	2Q17	3Q17	4Q17	1Q18	2Q18
FreeStyle Libre User Base	Global	"about 300,000"	~350,000 ³	400,000+	~450,000	650,000+	800,000+
	US	0	0	0	~3,000 ¹	50,000+	~125,000 ⁴
	OUS	~300,000	~350,000	400,000+	~447,000	600,000+	~675,000 ⁴
Estimated sensor-only sales, assuming ~90% utilization	Global	~\$90 million	~\$115 million	~\$130 million	~\$146 million	~\$212 million	~\$263 million
	US ²	\$0	\$0	\$0	~\$1 million	~\$18 million	~\$45 million
	OUS ³	~\$90 million	~\$115 million	~\$130 million	~\$145 million	~\$194 million	~\$219 million

1. Close Concerns' estimate; 2. Assuming ~10% of US patients obtain FreeStyle Libre through Medicare (~\$240/user/month sensor pricing) and 90% obtain it commercially (~\$120/user/month sensor pricing); 3. Assuming ~\$120/user/month sensor pricing, not including readers; 4. Assuming increase in user base was evenly split between US and OUS given ~50/50 division in share of total revenue growth. We note these sales figures exclude reader sales.

- FreeStyle Libre Revenue Assumptions:

- User base (~800,000 globally): We've used the publicly announced global FreeStyle Libre user base figures when possible.** For this roundup, this is 650,000+ global users (1Q18) and 800,000+ users (2Q18). By geography, we've estimated 2Q18 included ~125,000 US FreeStyle Libre users (up 150% sequentially from ">50,000" in 1Q18) and ~675,000 OUS FreeStyle Libre users (up 13% sequentially from 600,000 in 1Q18). It's unclear how Abbott defines a "user," which would obviously have utilization and revenue implications.
 - Pricing: Our 2Q18 model assumes ~10% of US Libre users are obtaining the system through Medicare at the higher pricing of ~\$8/user/day (Libre**

received Medicare reimbursement in January), and Abbott realizes ~\$4/user/day in revenue for the remaining US and international users. Combined with the user base figures noted above, this puts Libre 2Q18 global revenue with 90% utilization at ~\$263 million, a 90% YOY rise. The \$4/user/day pricing estimate for commercial/cash-pay users (i.e., non-Medicare) sensors may be overshooting Abbott's realized revenue, since we've previously reported [sensor net price](#) to be <\$3.60 per day. That said, our revenue calculations do not take reader sales into account, so the inflated sensor revenue estimate may be somewhat compensatory. The pricing obviously also does not account for discounts, different geographies/currencies, payer relationships, etc. Still, we note that our FreeStyle Libre sales estimate roughly backs out when comparing to Dexcom's revenue/patient, and our US Libre model is tracking well to CEO Miles White's [guidance](#) for \$90-\$100 million in US Libre revenue for all of 2018.

- **Utilization:** We're assuming that 100% Libre sensor utilization is unlikely - i.e., every user outside the US buying two sensors per month, and every US user buying three sensors per month. Our model estimates 90% utilization, which reflects the vast majority of users (but not all) wearing Libre 100% of the time.
- **What we still don't know or haven't estimated:** How does Abbott define a "user" - are all of these people currently wearing and ordering FreeStyle Libre, or is this base those who meet broader conditions - e.g., those who have ordered from Abbott at least once, but may not be wearing the system now. If the latter, revenue would obviously be less. How widely used is FreeStyle Libre Pro, and does the worldwide "user" number include professional sensor wear? (We assume not, but aren't sure.) We're also unsure of how pricing differs (if at all) in cases where FreeStyle Libre is reimbursed - presumably Abbott receives less than ~\$120/month in these cases. Last, we haven't accounted for sales from readers (~\$60 each), though assume they are small - especially with FreeStyle LibreLink apps available outside the US. In the [2Q18](#) call, the geographic split of Libre users was not provided. We assumed that the increase in Libre user base was evenly divided between US and OUS markets, given that the share of growth was roughly 50/50 (US: 53%; OUS: 47%).
- **Dexcom's sales totaled \$184 million in 1Q18 (+30% YOY) and a blowout record-high \$243 million in 2Q18 (+42% YOY).** Dexcom has now had three record sales quarters out of the last four, with 2Q18 clobbering the previous \$221 million record in [4Q17](#). Worldwide sales grew a remarkable 32% sequentially in [2Q18](#), the largest Q2 sequential gain Dexcom has seen since 2010. Notably and surprisingly, the acceleration came from G5, as G6's full US launch was only ~three weeks long in Q2 (it started in early June) - this bodes extremely well for 2H18. Both geographies saw record-highs: (i) US sales of \$190 million grew 35% YOY and 30% sequentially in 2Q18, Dexcom's strongest US growth in two years and driving 68% of 2Q18 growth; and (ii) international revenue of \$53 million grew a robust 78% YOY as reported (+71% operationally) and 36% sequentially, hitting a record 22% of Dexcom's total sales and driving 32% of growth. In a massive guidance raise, 2018 revenue is now expected at "approximately \$925 million," reflecting 29% YOY growth from 2017 and up a remarkable ~\$70 million from [1Q18](#)'s guidance range for \$850-\$860 million (+19%) in full-year sales. Dexcom has its hands full with the G6 global launch and has not shared expectations for any major new pipeline launches in 2018; the biggest one beyond G6's rollout is Tandem launching Basal-IQ in August. Read our [Dexcom 2Q18 report](#).
- **We estimate Medtronic's worldwide CGM sales totaled ~\$161 million in 1Q18 (up ~26% YOY) and ~\$143 million in 2Q18 (up ~27% YOY).** Estimated US CGM sales were ~\$93 million in 1Q18 (+22% YOY) and ~\$81 million in 2Q18 (+33% YOY), slightly larger than international sales of ~\$69 million in 1Q18 (+32% YOY) and ~\$62 million in 2Q18 (+20% YOY). Medtronic does not specifically break out CGM vs. pump sales, but the company did confirm with us last year that roughly ~25% of its Diabetes sales come from CGM, up from ~20% as of late 2015. The mix presumably varies from quarter to quarter and by geography; we've applied a straight 25/75 split to the US and international sales to derive the CGM/pump estimates in our model. If we had to

guess, we may be underestimating Medtronic CGM sales, given the faster growth in this area. Indeed, Medtronic reported in [2Q18](#) that it saw "nearly 50%" YOY sales growth in CGM - much higher than our model has - but it was unclear if that referred to professional/standalone CGM only (i.e., iPro 2, Guardian Connect) vs. all CGM sales including those that pair with pumps (e.g., 640G/Enlite 2, 670G/Guardian Sensor 3). In any case, Medtronic has a number of tailwinds that should pave the way for strong CGM sales in 2H18. First, the MiniMed 670G/Guardian Sensor 3 saw several milestones in Q2: (i) >97,000 trained, active users, a 38% gain from 1Q18's >70,000 (strong momentum); (ii) a CE Mark announced [in June](#) (launch "this fall" in 10 EU countries - likely the first AID system to the EU market); (iii) [FDA approval](#) for 7-13 year-old patients (likely some pent-up demand here); and (iv) [announcement](#) of the \$25,000 670G Outcomes Guarantee for Payers ("strong payer interest"). In addition, the Guardian Connect mobile CGM and paired Sugar.IQ app with IBM Watson launched in [June in the US](#), marking Medtronic's first foray into the competitive standalone US CGM market. CEO Omar Ishrak said in [2Q18](#) that the standalone CGM has "launched extremely well." No metrics were provided, but we have to imagine the company will capture at least *some* US market share; how much will be fascinating to see, as it will likely rest on pricing, payer relationships, and great marketing of the Sugar.IQ app and Guardian's predictive alerts. (Relative to FreeStyle Libre and G6, Guardian Connect has several disadvantages: it needs two fingersticks per day, seven-day wear, it is not on Android, and it doesn't have Medicare reimbursement.) Read our [Medtronic 2Q18 report](#).

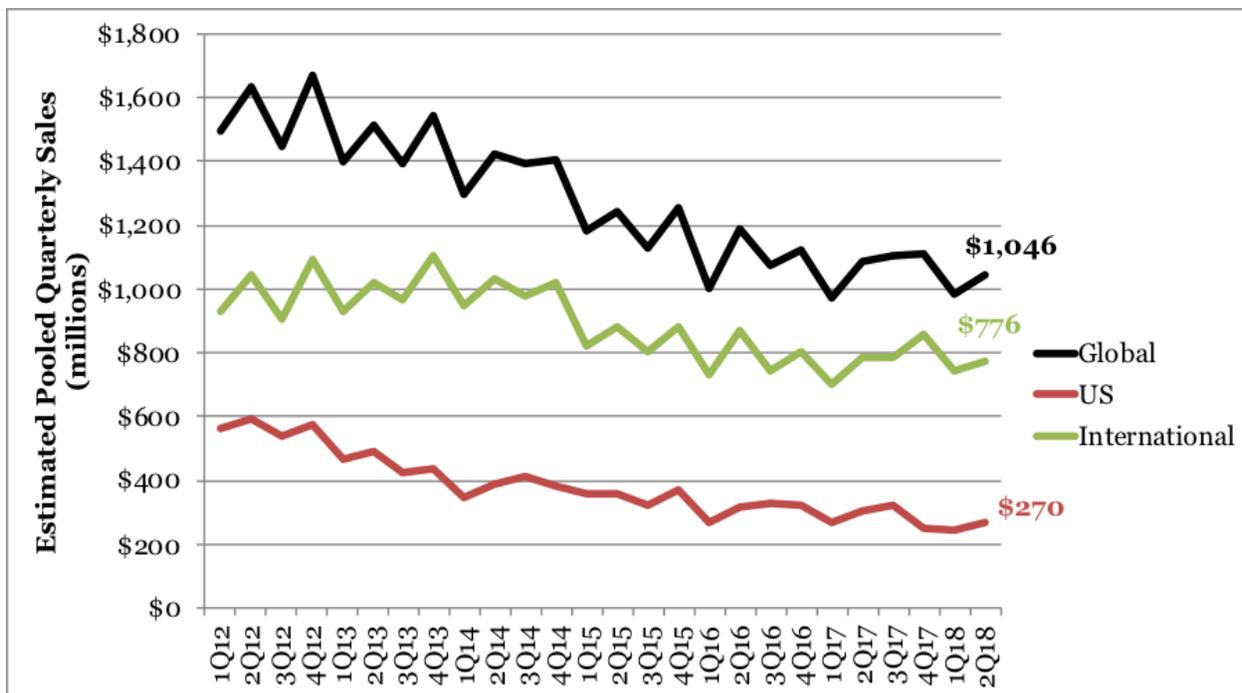
- **Senseonics reported revenue of \$2.9 million in 1Q18 and \$3.6 million in 2Q18, marking six straight quarters of sequential gains after \$300,000 in initial 4Q16 sales (the first quarter when revenue was reported).** 2Q18 sales quadrupled from 2Q17's \$0.8 million. Strong EU performance (38% installed base growth) and early commercial progress in the US prompted a slight 2018 sales guidance raise by \$1 million on both ends - now \$19-\$21 million (tripling YOY). July 31st marked the first US Eversense insertions, and we estimate that the global installed base is just under 4,000 users (up 38% in 2Q18). BCBS NJ is the first US payer to cover Eversense (UHC's recent [Medical Policy](#) deems it "unproven" and "not medically necessary"), and >80% of US users to date have come from Dexcom (though as [of the August call](#) it was only *one week* into the launch and arguably not that representative of what's to come). Internationally, 75% of 2Q18 revenue came from Italy, Germany, and Sweden, 70% of the installed base is on the 180-day XL sensor, and the Roche distribution agreement expires at the end of the year (we'd guess it will be renewed, since this is Roche's best CGM play at this stage). On the pipeline, Senseonics planned to submit a single PMA supplement to the FDA for non-adjunctive dosing and one-calibration per day - as of the August 8 call, the submission was expected "within a month." IDE submission for a 180-day Eversense XL US clinical trial is expected this month, with the study anticipated to start "in the coming months" (i.e., fall) and go well into 2019. Excitingly, Dr. Goodnow also mentioned that a trial with a 365-day Eversense is expected to begin in 1H19, referencing "tremendous progress" on in-vivo stabilization over one year - that would be remarkable, though is likely a late 2020 approval at the very earliest. Obviously it is still early days for Senseonics, though the company has executed nicely and there is certainly a big market to tackle! Read our [Senseonics 2Q18 report](#).

BGM

Roche, J&J, and Abbott Pooled BGM Sales Total ~\$2.0 Billion in 1H18, Down ~1% YOY; Has the OUS Market Stabilized?

BGM Sales by Geography, Estimated (1Q12-2Q18)

Roche, Abbott, J&J



Pooled global BGM-only revenue for Roche, J&J, and Abbott totaled an estimated \$985 million in 1Q18 (+2% YOY) and an estimated \$1.0 billion in 2Q18 (-4% YOY). Both came on easy comparisons to declines of 3% and 8% in 1Q17 and 2Q17, respectively. 1H18 estimated BGM sales for the three companies totaled ~\$2.0 billion, falling ~1% YOY from 1H17. BGM revenue has continued to drop steadily since its peak in 2011 - we estimate that pooled sales for these three companies have decreased ~36% between 2Q12 and 2Q18. J&J has been hit the hardest, declining ~43% between 2Q12 and 2Q18, followed by Abbott (-37%) and Roche (-29%). Still, there are signs of potential recovery, particularly in the international market, which saw three consecutive quarters of positive YOY growth (3Q17-1Q18) albeit followed by a 1% YOY decline in 2Q18. The US BGM market continues to struggle, with seven consecutive quarters of YOY declines - punctuated by an 11% YOY decline in 2Q18. Overall, we estimate Roche accounts for the lion's share of BGM revenue for these three companies, contributing ~45% and ~46% of total sales in 1Q18 and 2Q18, respectively.

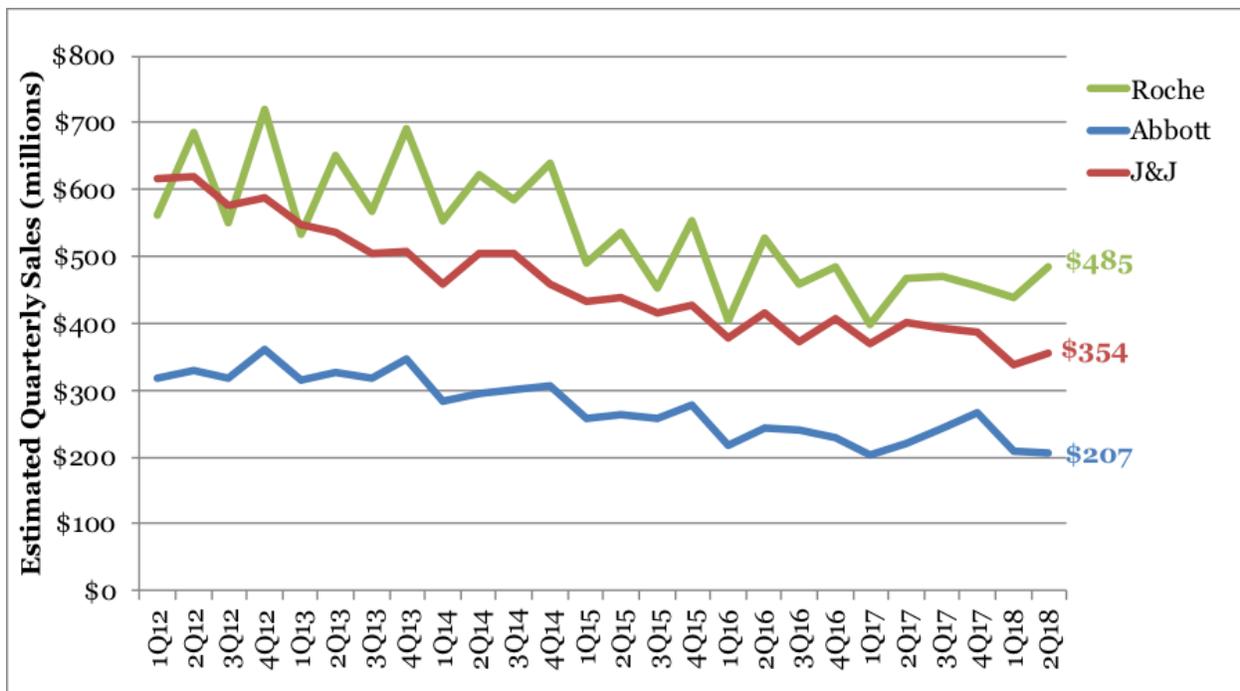
- **These BGM figures are highly estimated for Abbott, J&J, and Roche and do not include privately-held Ascensia (formerly Bayer and now part of Panasonic/KKR) or private companies (e.g., Livongo).** In addition to BGM, Abbott has FreeStyle Libre CGM, which we estimate is now running over \$200 million per quarter and larger than its legacy BGM business (see CGM section above). Roche has Accu-Chek pumps and revenue from Senseonics distribution and app revenue from mySugr, among other sources. Finally, our model estimates a tiny bit of residual Animas revenue (~\$2 million) from pump supplies distribution outside the US (given the [Animas exit](#) in October and Medtronic taking over in the US, we'll model this at zero going forward). See the CGM and pumps sections for specifics on our assumptions. BGM growth and sales might look better or worse than what we've reported here, depending on the accuracy of our assumptions within these other business segments.
- **International BGM sales totaled an estimated ~\$743 million in 1Q18 and ~\$776 million in 2Q18, rising ~6% YOY and falling ~1% YOY, respectively. Both came on easy YOY comparisons to 4% and 9% declines in 1Q17/2Q17.** Until 2Q18's 1% YOY decline, OUS revenue did see an encouraging three consecutive quarters of positive YOY growth. The graph above suggests the business is pretty stable - not declining significantly, but also not rebounding significantly. Pooled 1Q18 growth was driven by strong performances from estimated Roche BGM (+9% YOY) and Abbott BGM (+11% YOY). By our estimates, J&J BGM declined ~3% YOY. In 2Q18,

Roche was the only company to see positive YOY growth in BGM (+3% YOY), with [J&J](#) faring the worst (-10% YOY) and [Abbott](#) in the middle (-1% YOY).

- The US BGM market continues to struggle, with estimated pooled sales of \$242 million in 1Q18 (-9% YOY) and \$270 million in 2Q18 (-11% YOY).** The 1Q18 decline came on an easy comparison to flat YOY growth in 1Q17, and the 2Q18 decline came on an easy comparison to a 5% YOY decrease in 2Q17. US BGM sales have fallen or remained flat YOY in all but two of the past 26 quarters, highlighting the damage imparted by CMS's Competitive Bidding program, and likely the rising pressure in the BGM segment as more high-frequency strip users move to CGM. Roche was the only company to see positive YOY growth in the US, reporting estimated ~18% and ~6% YOY increases in [1Q18](#) and [2Q18](#), respectively. We assume the Accu-Chek Guide and Simple Pay Savings Program launched in the US [last May](#) is helping (very strong cash pricing for accurate strips), alongside the mySugr unlimited strips bundle with coaching (see [AADE](#)). Abbott and J&J saw US BGM declines in both 1Q18 and 2Q18, by our estimates - Abbott was down ~9% YOY and ~17% YOY, while J&J dropped ~19% YOY and ~15% YOY.

BGM Sales by Company, Estimated (1Q12-2Q18)

Global Sales: Roche, Abbott, J&J



- Roche had the strongest performance in 1H18, with estimated BGM sales of ~\$924 million rising ~7% YOY.** Sales were an estimated \$439 million in [1Q18](#) (+11% YOY) and ~\$485 million in [2Q18](#) (+4% YOY). See our [Roche 2Q18 report](#).
- J&J saw the largest declines in 1H18, with estimated BGM sales of ~\$691 million down ~10% YOY.** Sales were an estimated \$337 million in [1Q18](#) (-9% YOY) and ~\$354 million in [2Q18](#) (-12% YOY). See our [J&J 2Q18 report](#). As a reminder, J&J has [accepted](#) Platinum Equity's offer to acquire the LifeScan business for ~\$2.1 billion; the transaction is expected to close by the end of 2018, at which point LifeScan will be private under Platinum and we won't have visibility on this business.
- Abbott reported ~\$416 million in 1H18 BGM revenue by our estimates, down 2% YOY.** Sales were an estimated \$209 million in [1Q18](#) (+3% YOY) and ~\$207 million in [2Q18](#) (-6% YOY). Abbott does not break out FreeStyle Libre vs. BGM revenue, but our model now estimates FreeStyle

Libre is the larger business (>800,000 users globally); see the CGM section above. Read our [Abbott 2Q18 report](#).

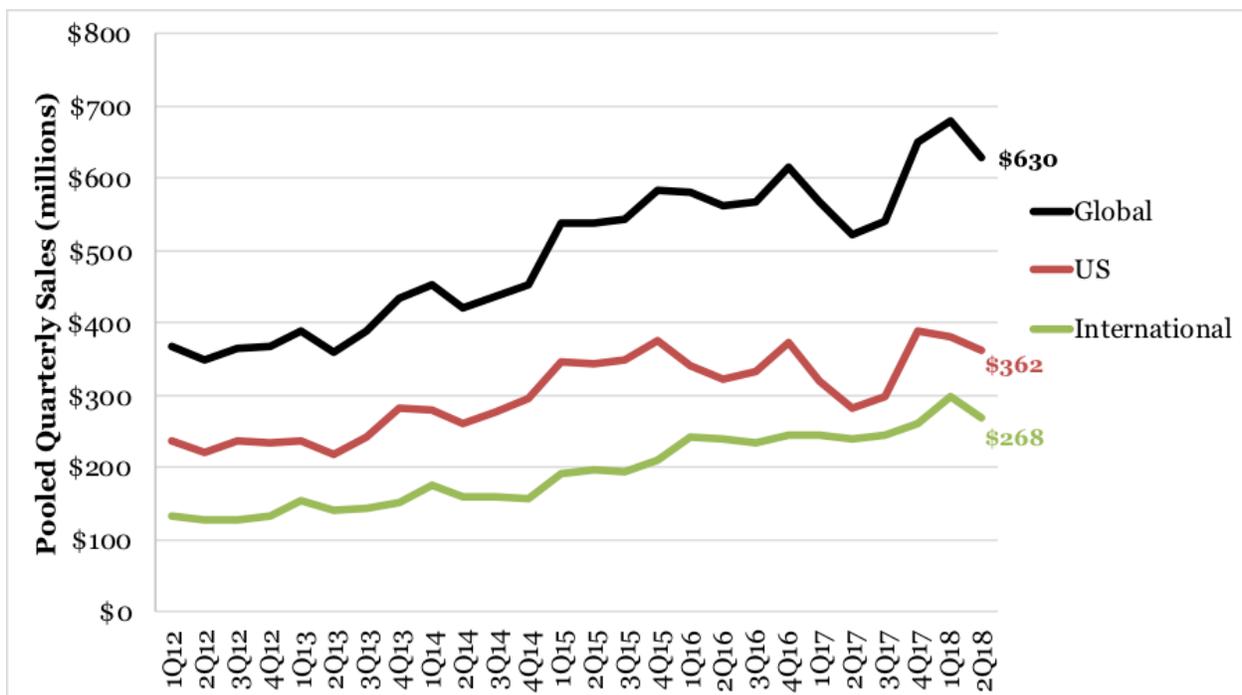
- **The traditional BGM market's future is uncertain, with several factors pushing companies to rethink their strategy and approach.** CMS's Competitive Bidding Program is partially responsible for the market's decimation, although rising CGM adoption amongst high-frequency users and the broader use of glycemic-dependent agents in type 2 diabetes (with much lower risk of hypoglycemia) may also be playing a role. With four standout CGM options now on the market, two of which are factory calibrated and indicated for non-adjunctive insulin dosing (Abbott's FreeStyle Libre and Dexcom G6), BGM companies will have to refocus and pivot - especially pushing earlier in the type 2 diabetes treatment paradigm where CGM has a long way to go. (Of course, professional CGM is also gaining ground in this group - yet more competition.) Business models may need to shift to being focused *around* devices - e.g., coaching, connectivity, education, insulin titration, and population management. More outcomes-based approaches will also be important, whereby BGM is provided as *one part* of a broader outcomes-driven program that combines or curates several tools. Smaller players like mySugr, Livongo, One Drop, and Dario have done great work to rethink the model, though a big question is how the larger legacy businesses will adapt and how quickly. (Roche has obviously taken a lead here by acquiring mySugr.) In our view, forming partnerships with payers and health systems will be key - using traditional BGM data and connectivity to fuel tools and generate insights around insulin titration, coaching, population health - rather than selling strips. Traditional BGM is not disappearing anytime soon, but traditional models will have to be creative in a declining market as real-time and professional CGM move towards standard of care.
- **Given the tough market drivers at play, Roche, Abbott, and J&J have been pushed to rethink their business strategies.** Roche has taken a clear stance by investing in its digital ecosystem, acquiring mySugr and partnering to distribute Senseonics CGM. Plus, Roche has the soon-to-be-launched patch pump, Solo (slated in [2Q18](#) for a controlled EU launch "for the remainder of the year), alongside its ambitions for automated insulin delivery with its tubed Accu-Chek Insight pump. Roche is also reportedly developing a professional version of mySugr, which was first introduced at [ATTD](#). The platform could emerge as a competitor to Glooko - what might Roche add to the increasingly crowded connected care landscape? Meanwhile, Abbott has firmly shifted attention to FreeStyle Libre, with no mention of its BGM business for quite some time; no surprise there. And last, J&J has decided to leave diabetes devices entirely; it accepted a ~\$2.1 billion offer from Platinum Equity to acquire LifeScan [in June](#) (the transaction is expected complete by the end of 2018) and CeQur acquired Calibra Finesse (OneTouch Via) from J&J [in July](#). The future of LifeScan will be fascinating to watch under the control of Platinum Equity - how will it compete? Where will it innovate? Despite struggles, the LifeScan BGM business still accrued net revenue of \$1.5 billion in 2017 - that sized business is not going to zero any time soon. What might [Platinum Equity](#), which lacks significant healthcare experience, do with the business? Will Platinum invest in a digital ecosystem to compete with Roche? Will it acquire players like One Drop, Livongo, Glooko, or WellDoc? Will it double down on the popular OneTouch Reveal app at the center of the diabetes business? Will Platinum acquire an earlier-stage CGM - [see our competitive landscape](#) for some candidates? What will happen to the WellDoc/LifeScan partnership? With the right investment, we think LifeScan can succeed; however, we'll lose the ability to track sales come 2019.

Insulin Pumps and Delivery Devices

1H18 Sales of ~\$1.3 billion up 20% YOY; Industry Record High in 1Q18 (~\$679 Million); Strong 1H18 for Medtronic (~72% of industry growth)

Insulin Pump Sales by Geography, Estimated (1Q12 - 2Q18)

Medtronic (estimated), Insulet, Tandem, Animas (estimated), Roche (estimated), Valeritas, and Cellnovo



We estimate the insulin pump and delivery devices market rose ~20% YOY in both 1Q18 (~\$679 million) and in 2Q18 (~\$630 million), marking three consecutive quarters of positive YOY growth for the industry. This includes sales from Medtronic (estimated), Insulet, Tandem, Animas (estimated), Roche (estimated), Valeritas, and Cellnovio. Both YOY increases came on easy comparison to declines of 3% and 7% in 1Q17 and 2Q17, respectively. 1Q18 was actually an industry revenue record (~\$679 million), handily surpassing the previous 4Q17 record of \$651 million. 1H18 pump sales totaled ~\$1.3 billion, rising 20% YOY. With the obvious exception of Animas, which has exited the pump market ([October 2017](#)), we estimate every company saw growth in both 1Q18 and 2Q18. Medtronic has carried the field in 2018, with an ~70% market share by sales and supplying ~73% of 1H18 pump industry growth - its highest contribution in nearly five years! Insulet and Tandem have also seen very strong revenue growth in 1H18, though with Medtronic's gains, both companies have made smaller contributions to global pump industry growth (~14% and 9%, respectively) than we saw in 2H17; see a company-by-company recap below. Overall, it's promising to observe this rebound from a very soft pump industry performance in 2017 - last year saw the first estimated yearly decline in pump industry revenue in our model going back to 2005, with most of the weakness coming in [1H17](#) (-6%) followed by a more moderate decline in [2H17](#) (-1%). We still see the pump market as somewhat fragile, as evidenced by Animas and Roche ceasing sales in the US in 2017. Still, with Medtronic, Insulet, and Tandem seeing excellent starts to 2018, two AID systems now in the US (670G, Basal-IQ), lots of international runway, and much more innovation to come (e.g., type 2 focused devices, mobile apps, next-gen AID systems with less burden, open protocol systems?), we expect pumps to see continued strength in 2H18 and beyond. In 2019-2021, we are also likely to see several potential new entrants in the US, including BD's type 2 patch pump (by September 2019), Bigfoot (~2020), Lilly (~2019-2020), and Beta Bionics (~2020), and potentially Ypsomed (FDA review ongoing), Sooil DANA, Cellnovio, and others. On the type 2-focused delivery devices front, Valeritas had a record 2Q18, and CeQur [acquired](#) J&J's Calibra Finesse (OneTouch Via) bolus patch device in July (launch expected in mid-2019).

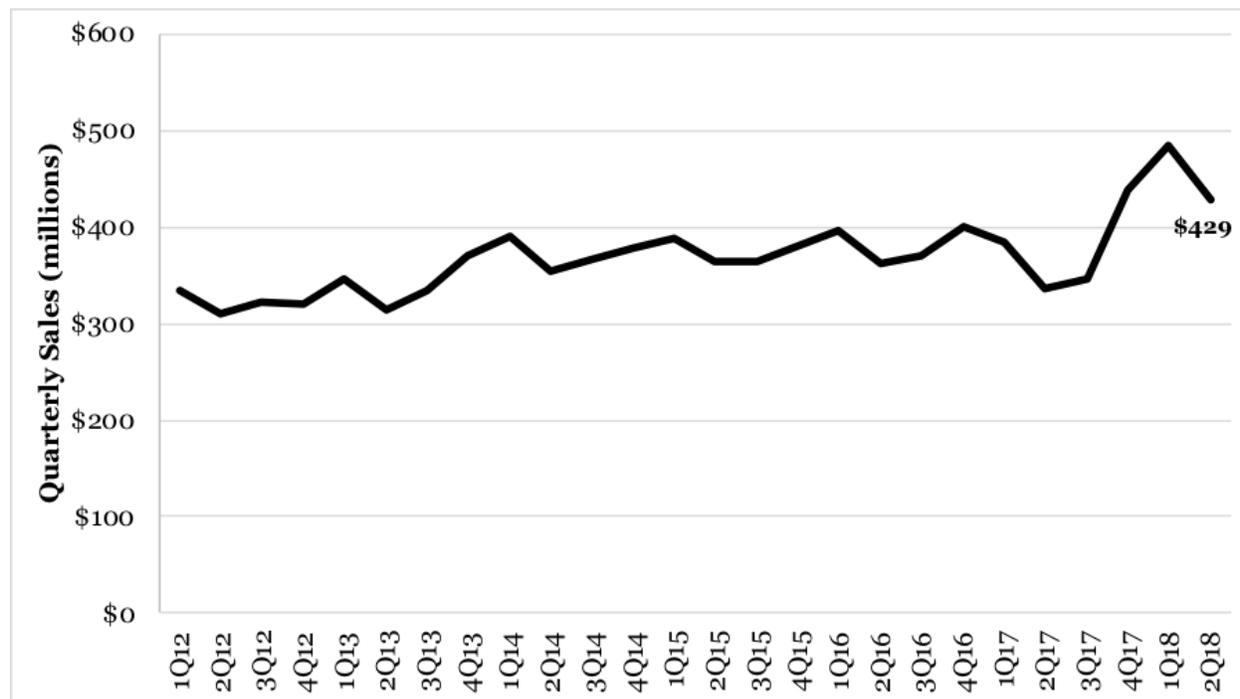
- Estimated US pump revenue totaled ~\$382 million in 1Q18 (+19% YOY) and ~\$362 million in 2Q18 (+28% YOY).** Both increases came on easy comparisons to declines of 6% and 13% in 1Q17 and 2Q17, respectively. (The easy comparisons were especially true for Medtronic, who still drives most of the pump industry's sales.) 2Q18 does mark three consecutive quarters of positive US growth, and notably, the US provided 74% of the industry's growth in 2Q18 - its strongest showing since 1Q15! Sales were driven by an especially strong half-year from Medtronic, who reported US growth of ~22% YOY and ~33% YOY in [1Q18](#) and [2Q18](#), respectively. Though

Medtronic's YOY comparisons were easy in 1H18, these strong gains supplied a very strong 69% of the US pump industry's growth in 2Q18. Medtronic's US pump growth, driven by strong MiniMed 670G uptake, seems poised to continue - per the company's [2Q18 call](#), there are >97,000 active 670G users (+38% from [1Q18](#)) and it now has pediatric approval in 7-13 year olds. Of course, Medtronic will have strong competition with Tandem's Basal-IQ/Dexcom G6 in 2H18 - that will be a fascinating battle to watch! Meanwhile, we estimate Tandem and Insulet each provided ~14% of the US pump industry's growth in 2Q18. Tandem saw 1H18 US sales of \$61 million grow an impressive ~58% YOY, while Insulet reported 1H18 US sales of \$148 million, up a slightly more modest 19% YOY on the higher base of sales. Insulet did see record-high US Omnipod sales of \$78 million in [2Q18](#), though the new Dash PDM won't make a material impact on revenue until 2019. We're likely to see Tandem's impressive performance continue, as Basal-IQ began shipping [in August](#) and we imagine many are excited to software upgrade to the Control-IQ hybrid closed loop currently in its pivotal trial (launch in Summer 2019). Read more company-by-company analysis below.

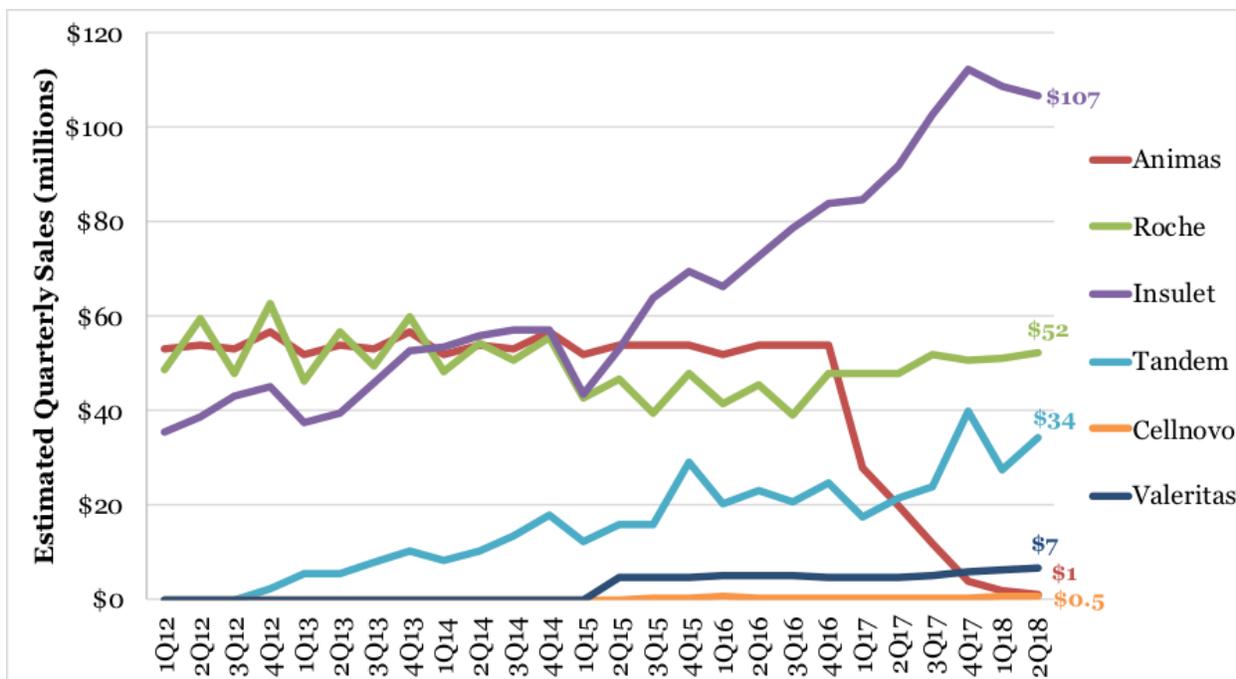
- Estimated international pump sales hit a record ~\$298 million in 1Q18 (+21% YOY) and totaled ~\$268 million in 2Q18 (+12% YOY).** Both gains came on fairly easy comparisons to 2% and 1% YOY growth in 1Q17 and 2Q17, respectively. 1H18 marks a return to double-digit international pump growth after four consecutive quarters of single-digit YOY increases. Even more so than in the US, Medtronic carried the OUS pump industry - its estimated sales were ~\$206 million in 1Q18 (+32% YOY) and ~\$186 million in 2Q18 (+20% YOY). Our model estimates Medtronic drove an impressive ~81% of OUS pump industry growth in 2Q18, even outpacing its 69% OUS pump market share (by sales). We should see continued Medtronic OUS pump growth during the latter half of the year, now that the 670G has a CE Mark and is expected to launch in 10 EU countries this fall. We estimate Roche contributed the second-largest share of OUS pump growth (~14%) driven by estimated international pump growth of ~12% YOY in 2Q18 (~\$52 million; this is highly estimated). Insulet's OUS business was marked by two very different quarters in 1H18: [1Q18](#) saw impressive 53% YOY growth (\$38 million), while [2Q18](#) saw weaker 7% growth (\$29 million) on inventory issues as it assumed direct EU distribution from Ypsomed.

Insulin Pump Sales By Company, Estimated (1Q12 - 2Q18)

Medtronic-only Global Sales (Pumps Only):



Global sales - excluding Medtronic - for Animas, Roche, Insulet, Tandem, Cellnovo:



- We estimate Medtronic's 1H18 insulin pump sales totaled ~\$913 million, rising 27% YOY.** Sales were an estimated ~\$484 million in [1Q18](#) (+26% YOY) and ~\$429 million in [2Q18](#) (+27% YOY). (As noted in the CGM section, this is based on an estimate that ~75% of Medtronic's sales are from pumps.) As of Medtronic's 2Q18 call [in August](#), the MiniMed 670G now has >97,000 active US users. Medtronic finally [obtained](#) CE Mark approval for 7+ years, and in the US, 670G approval for 7-13 years came [in June](#). Per CEO Omar Ishrak's comments during the [2Q18 call](#), Medtronic is "now just beginning to commercialize the 670G in international markets." The June timing expected an EU launch in 10 countries this fall, which should help continue the momentum seen in 1H18. See our [Medtronic 2Q18 report](#).
- Insulet's 1H18 sales totaled \$215 million, rising 22% YOY.** Sales were \$109 million in [1Q18](#) (+28% YOY) and \$107 million in [2Q18](#) (+16% YOY). [In August](#), management reduced full-year 2018 sales guidance to \$542-\$562 million (+18%-21% YOY), down ~\$18 million at the midpoint from previous guidance of \$565-\$580 million (+22%-25%). This deficit reflects international inventory headwinds related to Insulet taking over direct distribution from Ypsomed (see our [2Q18 report](#) for the full story). Per the [2Q18 call](#), Insulet expects the global Omnipod user base to hit ~167,000-177,000 by the end of 2018, reflecting growth of ~15%-26% - roughly in line with revenue. We'll be watching Insulet's US performance in 2H18 closely, as Tandem's Basal-IQ and Medtronic's MiniMed 670G will be tough competition. (Insulet would argue these systems aren't tailored for MDIs, which may be a fair point and we'll excited to watch the dynamics...) The next-gen Omnipod Dash system [commenced](#) its limited launch in July following FDA clearance [in June](#), though it's a fairly small launch and full rollout isn't expected until early 2019. See our [Insulet 2Q18 report](#).
- Tandem has had an impressive return to growth, reporting 1H18 revenue of \$61 million, up 58% YOY.** Sales were \$27 million in [1Q18](#) (+56% YOY) and \$34 million in [2Q18](#) (+60% YOY). Although the YOY comparison to a 7% decline in sales in 2Q17 was easy, 2Q18 revenue represented the second-highest sales in Tandem's history, only shy of the blowout record \$40 million in 4Q17. An impressive 5,447 pumps were shipped in 2Q18, a 59% YOY gain and a very strong 23% sequential rise. This brings the estimated "active installed base" to over 66,000 users (pumps shipped in the last four years), and total pumps since inception to over 78,000. "About half" of Tandem's organic new customers (i.e., non-renewal) came from MDI, similar to previous quarters

and a sign it is still expanding the market. The strong Q2 momentum came from early excitement for the software upgrade to Basal-IQ/G6 (launched in Q3 in mid-August), conversions from Animas and Medtronic patients, and 800 pump renewals from existing customers (more than doubling YOY). We expect to see continued strong growth from the company in 2H18, as Basal-IQ is the only Dexcom-G6 integrated pump in the US and brings a number of advantages over 670G (the PLGS interface/operation is much simpler, no alarms (if desired), no modes, touchscreen, factory-calibrated G6 CGM, remote software updates, Bluetooth, CGM remote monitoring via G6 app, etc.). Tandem also expects to commence international sales in 2H18 - while those won't be transformative, they will certainly be additive. See our [Tandem 2Q18 report](#). We'll hear more about its AID and international strategy on Tuesday at the company's first-ever Analyst Day.

- **We estimate Roche saw ~8% YOY pump growth in 1H18 on estimated insulin delivery sales of ~\$104 million.** Sales were an estimated ~\$51 million in [1Q18](#) (+7% YOY) and ~\$52 million in [2Q18](#) (+9% YOY) - all from outside the US. Roche has never split out pump sales specifically, so we're relying on measuring a bar graph from [Roche's 2Q18](#) slide deck, which shows its "Other" category (mostly pumps as far as we know) as contributing ~10% of total 1H18 revenue. It's possible that we have overestimated Roche's 1H18 pump sales here and/or underestimated pump revenue in 1H17; if either is true, then its pump growth would obviously be lower. As of [July](#), Roche's Solo patch pump was slated for a pilot launch "in the coming weeks" in Austria, Poland, Switzerland, and the UK, [followed](#) by further launches in 2019 and filing for FDA approval "in the future." We have yet to hear any updates on the pilot launch and will be eager to see if and when it expands to full commercial scale. Read our [deep dive on Solo](#) for feature details and screenshots, and see our [Roche 2Q18 report](#).
- **Valeritas reported \$13 million in 1H18 revenue, up 34% YOY.** Sales were \$6.1 million in [1Q18](#) (+32% YOY) and a record-high \$6.5 million in [2Q18](#) (+35% YOY). Although Valeritas has yet to report international revenue, the 24-hour disposable basal-bolus insulin patch device V-Go launched in Australia and New Zealand [in August](#), with a subsequent launch in Italy expected later this year. On the company's [2Q18 call](#), CEO Mr. John Timberlake stipulated that "meaningful revenue" from the New Zealand launch (and likely Australia, which followed it) is not expected in the near term. We'd expect these international launches might eventually boost sales in 2019, as will Valeritas' connected V-Go SIM (Simple Insulin Management) accessory - US availability with Glooko integration is expected "by the end of 1H19." Read our [Valeritas 2Q18 report](#).
- **Cellnovo reported \$1.0 million in 1H18 revenue, rising 83% YOY.** Sales were \$0.5 million in [1Q18](#) (+123% YOY) and \$0.5 million in [2Q18](#) (+57% YOY). Cellnovo finally completed the transition to large-scale manufacturing of insulin cartridges with Flex [in June](#), enabling a 12-fold increase in annual cartridge production. It remains to be seen whether demand will rise to meet the expanded supply, or whether other headwinds, including competition from Medtronic, Insulet, and Roche will push back. Earlier this month, Cellnovo [announced](#) the EU launch of its Gen 3 system, which moves the handheld controller from a custom medical device to a locked down, consumer-grade color touchscreen Android phone. The company has historically had a hard time scaling, but perhaps these latest developments will get things in line for expansion. Read our [Cellnovo 2Q18](#) report.
- **While the MiniMed 670G is still the only hybrid closed loop system on the market, the automated insulin delivery landscape is going to shift quite a bit over the next two years.** In the US, Tandem launched Basal-IQ (PLGS) with Dexcom G6 [in August](#), including a free software update for current t:slim X2 users; a US launch of Control-IQ, Tandem's hybrid closed loop system with automatic boluses, is [expected](#) in "summer 2019." Bigfoot's US pivotal trial is [expected](#) to start in 2Q19 with an anticipated 2020 launch, while Beta Bionics' home-use bridging studies are [currently underway](#) at MGH with Senseonics' Eversense and at Stanford with Dexcom's G6. We assume Lilly's plan to launch its hybrid closed loop in ~late 2019-late 2020 is still on track. Internationally, the Medtronic 670G [received](#) its CE Mark and is initiating OUS commercialization now/soon, per 2Q18 remarks. As of ADA [in June](#), Diabeloop expected a launch in late 2018 in

France, the Netherlands, and Sweden. Meanwhile the EU pivotal trial for the Roche/Senseonics/Type Zero AID system is slated to begin testing patients in Europe in 3Q18, although we're not sure how [Dexcom's acquisition of TypeZero](#) impacts this trial.

- [Read our just-updated automated insulin delivery competitive landscape](#) for the latest timing details.
- **While the type 2 pump market is still extremely underpenetrated, there are several promising patch insulin delivery devices designed for type 2 on the horizon.** CeQur's [acquisition](#) of Calibra Finesse (One Touch Via) from J&J, the highly anticipated, bolus-only, disposable insulin patch device is slated for a US launch in mid-2019. CeQur's own basal-bolus PAQ device is expected to launch in the US in ~2020-2021. Meanwhile, BD's type 2 patch pump and Insulet/Lilly's U500 Omnipod (both with connectivity) are expected to launch by "September 2019" ([BD](#)) and in "2019" ([Insulet](#)) in the US - we expect both to be very strong and well-received devices. Sensile Medical, Verily, and Sanofi also announced a partnership [this summer](#) to develop and commercialize an "all-in-one" pre-filled, connected type 2 patch pump; no development timeline has been shared. We also wonder if Roche will move the Solo patch pump into type 2, given the emphasis on ease of use and sleek form factor. Can costs get low enough? Medtronic's type 2 focus has pivoted to CGM, a smart move since the potential market is far wider.

-- by Maeve Serino, Adam Brown, and Kelly Close