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**Tandem 3Q17 - Sales rise 15% YOY on early t:slim X2-G5 enthusiasm; Animas' exit drives "overwhelming" calls; PLGS pivotal underway; TypeZero launch delayed to 1H19 - October 26, 2017**

**Executive Highlights**

- **Sales** (non-GAAP) of \$23.7 million rebounded in 3Q17, rising 15% YOY and 11% sequentially. This represented Tandem's third highest sales ever, and the 15% growth broke a string of three straight quarters with YOY declines
- **Pump shipments** of 3,868 declined 0.7% YOY in 3Q17, and rose 13% sequentially from [2Q17](#). The user base is now over ~60,000 customers. Year-to-date, Tandem has shipped 10,111 pumps in the US - by our math, this might be outpacing Insulet's US Omnipod.
- **2017 sales guidance** was reduced - non-GAAP sales are now expected at \$95-\$100 million (~10% YOY growth), back from the previous \$100-\$107 million. The guidance feels quite achievable given several Q4 tailwinds.
- **Cash** at quarter's end was \$23 million. Combined with an [October raise](#) (+\$14.8 million), runway will extend into 2018. An additional fundraise is expected in 2018.
- **t:slim X2/Dexcom G5** integration [launched in late August](#) to a "fantastic response"- both to new customers and as a free remote software update to existing X2 users.
- **Animas' decision** to [exit the pump market](#) has helped Tandem - the sales pipeline has "increased dramatically." Tandem's call center has seen "pretty overwhelming" inquiries, which should be a positive for 4Q17 results, assuming the leads turn into shipments, which we expect them to - given Medtronic's supply issues and the decision not to offer in-warranty Animas users the MiniMed 670G.
- **A CE Mark** will be filed by the end of 2017, enabling t:slim X2 international sales to commence in 2018 in "select geographies." Canada is the #1 priority.
- **PLGS** with Dexcom G5 is still expected to launch in summer 2018. The pivotal trial (PROLOG) began [enrolling in August](#) and is on track to complete by the "end of the year."
- **Treat-To-Target with TypeZero** and Dexcom's G6 has been delayed - launch is now expected in the first half of 2019, back ~ six months from the previous "end of 2018."

Tandem [reported](#) 3Q17 results this afternoon in a call led by CEO Kim Blickenstaff. In one of its most eventful (and arguably highest pressure) quarters ever, the company delivered encouraging results on multiple fronts - 15% YOY sales growth, launch of the long-awaited t:slim X2/G5 integration, a successful rollout of t:lock, enrollment starting in its PLGS pivotal trial, and Animas' exit driving "overwhelming" call volume - all should help drive a big Q4.

To our surprise, full-year revenue guidance was reduced, and cash still remains a near-term concern - Tandem has enough resources for a couple quarters, with some upside from recent warrants. There are plans to raise more money in 2018.

On the competitive front, the 670G feels like less of a threat than a year ago (even if it were widely available, which it is not), and we expect Animas' exit to drive additional t:slim X2 shipments, particularly due to the decision not to offer all Animas users the 670G (or Guardian 3 sensor, at least near-term). We expect strong

4Q17 growth and sales, assuming Tandem can compete effectively with both Medtronic and Insulet in the year's final months.

Read the call's top highlights below, sorted by financials; t:slim X2/G5 and competitive dynamics; and product pipeline.

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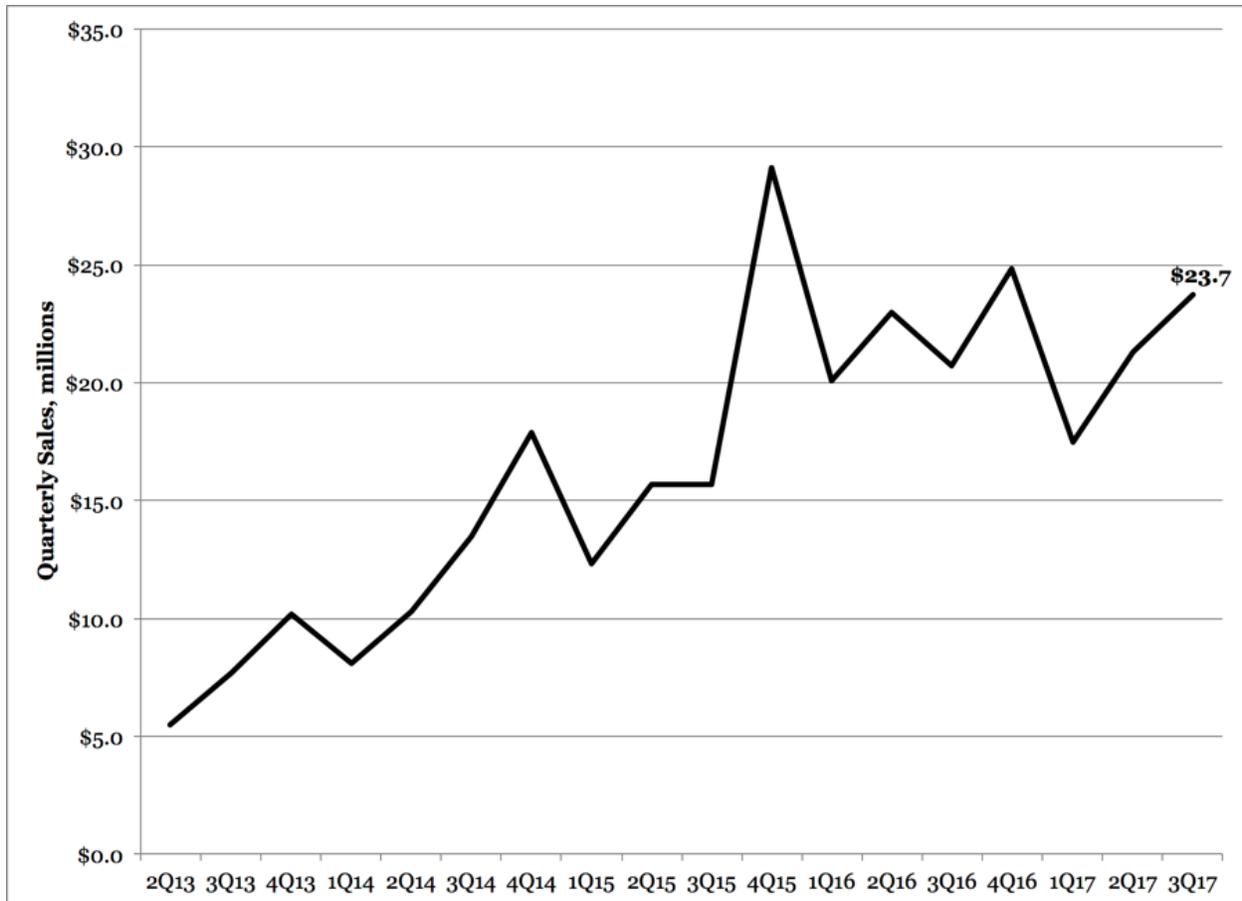
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### Financial Highlights

#### **1. SALES OF ~\$24 MILLION RISE 15% YOY AND 11% SEQUENTIALLY; THIRD HIGHEST SALES EVER BREAK STRING OF YOY DECLINES**

**Tandem's sales (non-GAAP) rebounded in 3Q17, rising 15% year-over-year (YOY) to \$23.7 million. Sales grew a strong 11% sequentially from 2Q17, the strongest Q2-to-Q3 gain Tandem has seen since 2014.** This represented Tandem's third highest sales ever, and the 15% growth broke a string of three straight quarters with YOY declines. That said, this was the easiest YOY comparison Tandem has had in 2017, as t:slim sales started to slow one year ago in [3Q16](#) (32% growth) following the 670G approval noise. Still, we interpret this as a strong quarter, since Tandem actually did not have much tailwind from the t:slim X2/G5 approval [in late August](#) - management said it typically takes at least 30 days to verify insurance and ship, meaning a lot of the upside from t:slim X2/G5 shipments will come in Q4 (more on this below). From a sales perspective, the business continues to hold steady in the face of a dynamic and competitive environment, though Tandem will need another big Q4 to instill confidence and pave the way for fundraising in 2018. (As a reminder, Tandem's non-GAAP sales exclude the impact of the new technology upgrade program, which gives a better sense of the underlying business.)

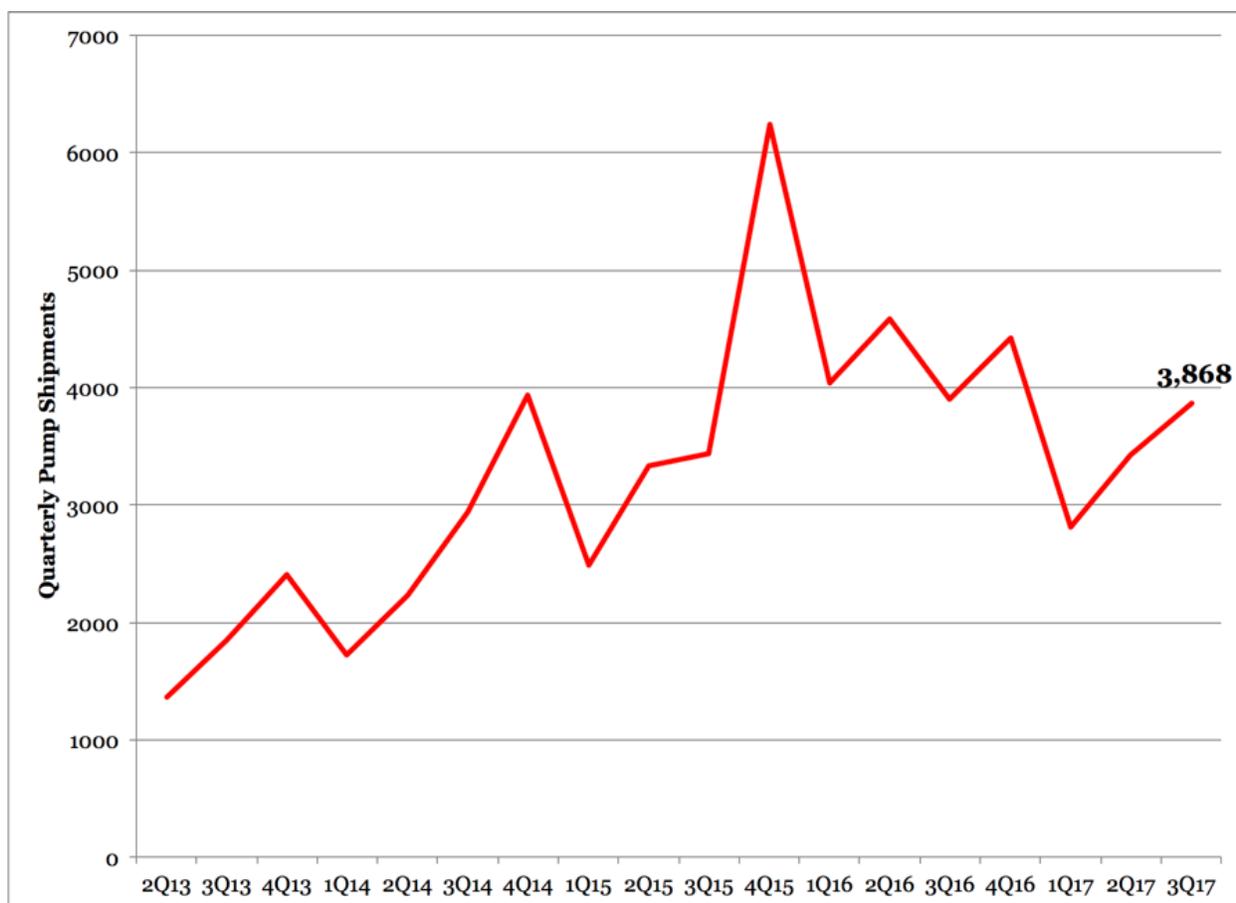
**Tandem Quarterly Sales (2Q13-3Q17)**



**2. PUMP SHIPMENTS DOWN 0.7% YOY, BUT UP 13% SEQUENTIALLY; BASE ~60,000 USERS; ARE TANDEM'S US PATIENT ADDS OUTPACING INSULET?**

**Pump shipments of 3,868 declined 0.7% YOY in 3Q17, but rose 13% sequentially from 2Q17.** The user base is now over ~60,000 customers, though this milestone was not specifically mentioned today. There was also no mention of the percentage of patients coming from MDI - recently it has been ~60% - which could mean that more pumps in 3Q17 were shipped to current pumpers (i.e., more of a 50%/50% split). This would align with the t:slim X2/G5 approval, as we assume many early adopters on pumps were waiting for that approval.

- Year-to-date, Tandem has shipped 10,111 pumps in the US - by our math, this might be outpacing Insulet's US Omnipod business.** Insulet has guided for 15% YOY growth in its US installed base in 2017, which would take it from ~67,000 users at the start of the year to ~77,500 by the end of the year. Assuming equal patient adds per quarter (a generous assumption, since Q3-Q4 tend to be bigger) and growth in line with guidance, Insulet is adding ~2,500 patients per quarter, or ~7,500 in the US in 2017. If true, that's actually ~25% less than Tandem's year-to-date performance.



**3. 2017 SALES GUIDANCE REDUCED FROM \$100-\$107M TO \$95-\$100M (~10% YOY GROWTH); FEELS VERY ACHIEVABLE (POSSIBLY CONSERVATIVE)**

Despite management's enthusiasm, we were slightly surprised to see 2017 sales guidance reduced - non-GAAP sales are now expected at \$95-\$100 million (~10% YOY growth), back from the previous \$100-\$107 million. Management also gave GAAP revenue guidance for the first time in 2017, which includes the impact of the new technology upgrade program (it ended in September): sales of \$100-\$105 million, reflecting 22% YOY growth from 2016 at the midpoint. Tandem is ~64% of the way to the non-GAAP 2017 guidance and ~66% of the way to GAAP guidance, in line with 2014 and 2015 (last year was an exception, as 49% of sales came in 1H16).

- **To us, both guidance ranges feel achievable and possibly conservative, given several Q4 tailwinds:** a full quarter of t:slim X2 G5 launch (3Q17 had just one month), typical Q4 seasonality, presumably some Animas patients coming over to Tandem (more below), more infusion set revenue as t:lock rolls out completely, and Tandem's largest number of four-year warranty expirations available for renewal. Tandem also has a very easy comparison coming up - 4Q16 sales declined 15% YOY, meaning 4Q17 should show very strong YOY growth.

**4. \$23M IN CASH ON HAND + \$15M OCTOBER RAISE = RUNWAY INTO 2018; ADDITIONAL FUNDRAISING TO OCCUR IN 2018**

Tandem has \$23 million in cash on hand, reflecting net cash use of \$19 million in 3Q17. Combined with an [October raise](#) (~\$15 million in net proceeds), Tandem's runway will extend into 2018 (quarter not specified). Tandem plans to raise additional capital in 2018 - we assume this might happen early in the year, as current resources will last ~two quarters at the current burn rate. On the plus side, [October's raise](#) also included two series of warrants, which would provide Tandem up to an

additional \$16 million each, assuming they are exercised before their expiration dates (April 2018 and October 2023). The nearer-term warrants expiring in April would be a nice win for Tandem near-term. Tandem did have a couple adverse cash factors in 3Q17 - building t:lock inventory, new pumps shipped late in Q3 where cash has not been collected - implying (to us) that burn should improve in 4Q17. Of course, higher sales will also help in Q4. The call was vague on potential fundraising vehicles, only saying "different financing alternatives" are being explored and a "stair step approach may be pursued." A big Q4 will go a long way towards instilling investor confidence.

- **Tandem estimates its US pump market share is at ~10% (same as 2Q17), and believes this will increase to ~11% by year end. In line with 4Q16, management believes sustained profitability could come at a market share of 15% and gross margins of 55%.** Management still expects this could come in 2019, implying a very significant bump in gross margin from the current level of 44% (GAAP basis). Tandem told us this estimate assumes a constant US pumper base of ~550,000, meaning it must only add ~25,000 patients to the base by 2019 - very doable if it continues at the current rate of ~3,000-4,000 per quarter. This also implies a one-percentage point in market share in Q4 would add 5,500 patients. The gross margin piece will be harder for Tandem, but doable if the business can scale - a big "if" given the recent history in insulin pumps. We look for the market to expand dramatically when automated insulin delivery emerges more fully.

**t:slim X2/G5, Competitive Dynamics, and t:lock**

## **5. T:SLIM X2/G5 LAUNCHES IN AUGUST TO "FANTASTIC" RESPONSE; 1/3 OF X2 USERS UPGRADED AT HOME TO ADD G5; FREE UPDATES PROMISED FOR 2018 FDA APPROVALS**

**Immediately following FDA approval, the t:slim X2 with Dexcom G5 integration [launched in late August](#) - both to new customers and as a free remote software update to existing t:slim X2 users. The response has been "fantastic" and "overwhelmingly positive."** Within the first month, one-third of t:slim X2 users updated their pumps software at home (via the Tandem Device Updater) to add G5 integration - an exciting new paradigm for rolling out pump innovations. Of those who updated, 85% said they were "satisfied" or "extremely satisfied," which does not surprise us - the [demo we saw at ADA](#) revealed a very strong user experience. Notably, most upgrades happened just 2.5 weeks post announcement, remarkably fast. In Q&A, management said the upgrade rate was in line with expectations - Tandem estimates that roughly ~30-35% of its pump users are on CGM. ("We never thought it would be 50%" upgrading.)

- **Notably, [earlier this week](#) Tandem announced that t:slim X2 users will also get "free" software upgrades to any new products the FDA approves in 2018.** This allows Tandem to de-risk the fear of choosing a pump, since users know they'll get the next-gen innovation without having to pay thousands of dollars out of pocket for an upgrade (or wait until four years have elapsed on their warranty). The expansion is a clear competitive move in advance of Tandem's Predictive Low Glucose Suspend (PLGS) device - the product is [in its pivotal study](#) and expected to launch in summer 2018 (see below). Management believes the t:slim X2's updateability will differentiate it from the competition, a sentiment we agree with - at least for now. We know Medtronic has Bluetooth-enabled pumps in the pipeline, though specific timing has never been shared. Similarly, Insulet has potential for remote software updates with Omnipod Dash (FDA submission in 4Q17), though this has never been a focus in discussions on the product. Bigfoot expects a launch in 2020 (pivotal in 2018 with Abbott's FreeStyle Libre) and has talked similarly about remote software updates.

## **6. ANIMAS EXIT DRIVES DRAMATIC INCREASE IN TANDEM'S SALES PIPELINE, "OVERWHELMING" INQUIRIES; SHOULD DRIVE UPSIDE IN Q4**

**Following Animas' decision to exit the insulin pump market ([three weeks ago](#)), Tandem's sales pipeline trajectory has "increased dramatically" relative to earlier in the year. The call center**

has seen a "pretty overwhelming" number of inquiries - this should be a positive for 4Q17 results, assuming many of these leads turn into actual shipments. As a reminder, Tandem announced [earlier this week](#) an expanded welcome program - Animas users with ~two years left on their pump warranties can get on the t:slim X2 for a fully refundable deposit of \$999 (i.e., a free upgrade, assuming they stay on t:slim X2). Insulet's program is slightly more generous in terms of upfront cash, as it offers a free switch to the Omnipod AND 10 free pods. However, Tandem's program extends to March 31, 2018, while Insulet's program expires two months earlier. Both companies have partnered with Dexcom to offer a \$200 cash gift card (from Dexcom) for those completing a "patient survey" and upgrading to G5 (i.e., new to CGM or currently on G4). We'll have to see how Tandem and Insulet both do in 4Q17; we'll hear Insulet's take on the competitive landscape in next week's call.

- **Though Medtronic is technically the "[partner-of-choice](#)" for the Animas transition, we expected the news would be a net positive for Tandem for the reasons listed below.**
  - **G5 integration:** Tandem has the only G5 integrated pump right now, and we'd guess a fairly meaningful number of Animas/Dexcom users will move over to t:slim X2/G5 instead of Medtronic since we believe most Dexcom users do not want to move to the Medtronic sensor, certainly not the "old" Enlite sensor, which is what the offer is at *present*. (Medtronic told us it will upgrade the 630G to Guardian Sensor 3 in the Spring.) Insulet has not shared plans to put G5 data on the Dash PDM until the Horizon automated system launches, so Tandem has some nice lead time on this front.
  - **One less large competitor** in the field should be a plus for Tandem, who now only has to compete with Medtronic and Insulet. That's still a tall order, but it's less onerous than having J&J in the mix too.
  - **User base up for grabs:** CEO Kim Blickenstaff estimated that roughly half of Animas' ~90,000 users are in the US. That means if ~10%-20% of them opt for the t:slim X2, it would be ~4,500-9,000 patients, a nice tailwind on top of Tandem's current ~60,000 users. Assuming Tandem successfully expands into Canada in 2018, there is further upside. The Animas base overseas is not changing from Animas immediately, though we expect this near term. We're not sure why Animas isn't exiting other markets immediately, but perhaps it's related to distribution, margins, or less competition in other countries.
  - **De-risking choice with the Tandem Device Updater + free upgrade promise for 2018 FDA approvals.** As noted, this is key for the upcoming PLGS device. Plus, it is far better for the portion of Animas patients being offered a free upgrade to Medtronic's MiniMed 630G - that device only offers low glucose suspend, isn't an option until May 2018, and does not have a free upgrade path beyond it - the latter is particularly surprising, but this was clearly negotiated as part of the exclusive arrangement between Medtronic and J&J. As noted in the [Animas exit piece](#), the free 630G upgrade applies to Animas users with warranties expiring ~two or more years from now (on/after September 30, 2019).
- **Given Medtronic's ongoing manufacturing challenges, the MiniMed 670G still hasn't broadly launched - making it seem like less of a near-term threat to Tandem.** Medtronic [announced last week](#) in an HCP email that due to global sensor demand and storm-related manufacturing disruptions in Puerto Rico, the company's manufacturing remains quite constrained - we believe this is true for other reasons as well. Patients in the 630G-to-670G Priority Access Program can now expect to receive pumps and transmitters in the second half of November, with Guardian 3 sensors to follow "soon" after, based on patients' sensor re-order date. For those with new 630G or 670G orders, pumps are now expected to ship by the end of October, with sensor and transmitter orders expected to ship by the end of 2017/early 2018 (which is more vague than some patients would like). Though patients are still having a tough time choosing between devices, it's a clear positive for Tandem that the MiniMed 670G has been approved for over a year but not yet broadly launched.

## **7. T:LOCK LAUNCHES AS EXPECTED, HELPING INCREASE SET REVENUE FROM \$5M TO \$13M YEAR-TO-DATE; SETS BOUGHT DIRECT FROM TANDEM UP TO 66%**

**As expected, Tandem began shipping t:lock in 3Q17, its new custom infusion set connector.**

**Impressively, it's already helping drive gains in revenue:** year-to-date sales of infusion sets are ~\$13 million, nearly tripling the ~\$5 million at this point in 2016. There's also been a "substantial" increase in the percentage of sets purchased directly from Tandem, up to 66% in 3Q17 - this is a bump from 61% in 2Q17, more than doubles the 27% one year ago (3Q16), and more than triples the 18% two year ago (2015). Management said it is "pleased with the progress," and the percentage is expected rise to nearly 100% by year-end - patients with Luer Lock supplies will need time to use them up and switch over to t:lock.

- **t:lock replaces the Luer Lock connection between the cartridge and infusion set and has three advantages:** (i) higher revenue, as distributors will have to buy sets from Tandem instead of other suppliers (from [Tandem's ADA Media Day](#), we learned they typically buy sets in bulk from Animas at a lower price); (ii) reduces the time required to fill the infusion set tubing by more than 30 seconds; and (iii) reduces the amount of insulin used in the process by approximately four units. **This is a great example of a product improvement that also drives the business.**

### **Product Pipeline**

## **8. CE MARK FILING BY END OF 2017 ENABLING SELECT 2018 INTL LAUNCH; CANADA LAUNCH #1 PRIORITY**

**In line with [2Q17's](#) announcement, Tandem is on track to file for CE Mark by the end of 2017, enabling international sales to commence in 2018 in "select geographies."** Canada is the #1 priority, a strategic move given the Animas exit. (We're not sure how many Animas users are in Canada, but assume it is a meaningful number.) Health Canada filing timing was not shared, though it sounds like there is a lot of work to be done - French translation was specifically mentioned. More timing is expected by the next call.

## **9. PLGS PIVOTAL ENROLLING, EXPECTED END OF 2017 COMPLETION; SUMMER 2018 LAUNCH**

**Launch of Tandem's predictive low glucose suspend (PLGS) device with Dexcom G5 integration is still expected in summer 2018** (in line with the [2Q17 update](#)). The pivotal trial (PROLOG) began [enrolling in August](#) and is on track to complete by the "end of the year." [ClinicalTrials.gov specifically](#) says "November," though "end of year" was used today - we're not sure if that means things are ramping up slower than expected, or if management was being less specific.

- **The [PROLOG study](#) is a randomized crossover design comparing two three-week periods at home:** the t:slim X2/G5 with PLGS algorithm vs. t:slim X2/G5 with no automation. The primary endpoint is time <70 mg/dl at three weeks - thank you FDA! - which we expect to be a slam dunk win for PLGS. Patients 6+ years will be enrolled at five excellent centers (Stanford, UCSD, William Sansum, Barbara Davis, Yale), with the great Dr. Bruce Buckingham serving as PI and the Jaeb Center for Health Research coordinating the trial.
- **Inpatient feasibility data [at ADA 2017](#) looked strong, and we continue to see this as a low-risk product** with a proven algorithm, clear FDA path, and solid upside for Tandem to get a first-gen product to market quickly - whether it will compete effectively against hybrid closed loop systems like the 670G remains to be seen.

## **10. SECOND-GEN AID WITH TYPEZERO DELAYED ~6 MONTHS TO 1H19 LAUNCH; IDCL PIVOTAL STARTING IN 1H18**

**Launch timing has been delayed on the treat-to-target AID device with TypeZero - launch is now expected in the first half of 2019, back ~6 months from the previous "end of 2018" expectation.** This is not too surprising, as the NIH-funded international diabetes closed loop (IDCL) study

has been extremely slow to get off the ground - the three-month pivotal for Tandem/Dexcom/TypeZero is now expected to start in 1H18. As a reminder, it was [nearly one year ago](#) that Tandem shared IDCL would serve as its pivotal - at the time, an FDA submission was expected by the end of 2017! Clearly, it has taken longer than expected to get all the hardware and software and trial sites ramped up. The trial will use Tandem's t:slim X2 pump, Dexcom's G6 sensor, and the TypeZero treat-to-range algorithm built into the pump. It is obviously a major plus that this trial is NIH-funded, and Tandem may *still* be second-to-market in the US with a hybrid closed loop - Insulet expects a launch in 2019 (pivotal in 2018), Bigfoot expects a 2020 launch (pivotal in 2018), and Beta Bionics expects an insulin-only launch in the first half of 2020 (pivotal in 1H19). We would not be surprised to see some timeline estimates shift.

### Pipeline Summary

| Pipeline Product   | Timeline   |
|--|--|
| t:lock Custom Infusion Set connector   | Launched in 3Q17.  |
| Dexcom G5 CGM integration for the t:slim X2 Pump   | Launched in August 2017.   |
| Predictive Low Glucose Suspend (PLGS) for the t:slim X2 Pump   | Launch in summer 2018, assuming a six-month FDA review. 90-patient, five-site pivotal trial ( <a href="#">PROLOG</a> ) started enrolling <a href="#">in August</a> and expected to wrap up by the end of 2017. |
| Type Zero's TTT (treat-to-target) automated insulin delivery algorithm and Dexcom G6 CGM for t:slim X2                               | Launch in the first half of 2019. Pivotal trial ( <a href="#">IDCL</a> ) to start in the first half of 2018.   |
| Mobile app for mirroring t:slim X2 pump information  | Not mentioned on past two calls. <a href="#">Per ADA Media Day</a> a launch was possible by the end of 2017.   |
| t:sport<br><i>~50% smaller t:slim worn on the body, a short infusion set, and pump control via a wireless handheld or mobile app</i> | No recent updates. PMA submission previously expected in 2018, but this seems unlikely.  |

-- by Adam Brown and Kelly Close