ACCELERATE DIAGNOSTICS, INC

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) **August 3, 2017**

Accelerate Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-31822	**84-1072256**
(Commission File Number)	(IRS Employer Identification No.)
3950 South Country Club, Suite 470, Tucson, Arizona	**85714**
(Address of principal executive offices)	(Zip Code)

(520) 365-3100

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 3, 2017, Accelerate Diagnostics, Inc. issued a press release announcing its preliminary financial results of operations for the quarter ending June 30, 2017 and hosted a conference call to discuss such results. A copy of the press release is attached hereto as Exhibit 99.1 and a copy of the transcript of the conference call is attached hereto as Exhibit 99.2.

In accordance with General Instruction B.2 for Form 8-K, the information in this Item 2.02, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following materials are filed as exhibits to this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press Release, dated August 3, 2017
99.2	Preliminary Earnings Call Transcript, August 3, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ACCELERATE DIAGNOSTICS, INC.
(Registrant)

Date: September 27, 2017

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated August 3, 2017
99.2	Preliminary Earnings Call Transcript, August 3, 2017

Exhibit 99.1

Accelerate Diagnostics Reports Q2 2017 Financial Results, Doubles Revenue Generating Placements

TUCSON, Ariz., Aug. 03, 2017 (GLOBE NEWSWIRE) — Accelerate Diagnostics, Inc. today announced preliminary financial results for the quarter ending June 30, 2017. The company further reported signed agreements for 265 instruments year to date; contracts for customer evaluations have grown to 220 instruments while revenue generating placements have doubled to 45 across the U.S., European, and Middle East regions.

Net sales for the second quarter 2017 was $699,000 compared to $20,000 in the second quarter of 2016. The increase was driven by sales of the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

"This past quarter was quite exciting," said Lawrence Mehren, President and CEO. "Despite complicated budgets and verification requirements, enthusiasm for our solution remains high and customers, supported by a number of recent studies confirming the speed and accuracy of the system, continue to find ways to move to acquisition."

The company also reported completion of a multi-center pilot study for its lower respiratory kit, currently under development. The study provided early customer feedback and data for algorithm development using a protocol that aims to reduce diagnostic uncertainty for healthcare-acquired and ventilator-associated pneumonia by 1-3 days.

President and Chief Executive Officer, Lawrence Mehren, and Chief Financial Officer, Steve Reichling, will host a conference call to review the results at 4:15 p.m. Eastern Time on August 3, 2017.

Preliminary second quarter 2017 results

- Net sales of $699,000 compared to $20,000 in the second quarter of 2016
- Gross margin realized was 81% including inventory previously recorded as research and development (R&D) expense
- Selling, general, and administrative expenses of $11.5 million, compared to $9.5 million in the prior year period, driven by customer evaluation and personnel related costs
- R&D expenses for the second quarter of $5.5 million, compared to $8.4 million in the second quarter of 2016 due to clinical trial and pre-launch inventory costs incurred in the prior year period
- Net loss of $16.5 million, or $0.31 per share on weighted average basic shares of 53.6 million shares outstanding, which includes $4.2 million in non-cash stock-based compensation expense

- Net cash for operations, separate from the sale of stock, was $11.9 million, ending the quarter with total cash, cash-equivalents, and short-term investments from all activities of $135.2 million

Full financial results for the quarter ending June 30, 2017 will be filed on Form 10-Q through the Securities and Exchange Commission's (SEC) website at http://www.sec.gov . The company anticipates filing on August 7 th . Investors are cautioned not to place undue reliance on these preliminary estimates in the event of material changes.

Conference Call

The conference call will begin at 4:15 p.m. Eastern Time (1:15 p.m. Pacific Time) on August 3, 2017. The live teleconference of the call can be accessed through the company's website at http://ir.axdx.com .

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 8021823. International participants may dial +1.412.902.6506. Please dial in 10-15 minutes prior to the start of the conference. A replay of the call will be available by telephone at +1.877.344.7529 (U.S.) or +1.412.317.0088 (international) using access code 10108001 until August 17, 2017.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. ("Accelerate") (Nasdaq:AXDX), is an in vitro diagnostics company dedicated to providing solutions for the global challenge of antibiotic resistance and healthcare-associated infections. The company's Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit were recently cleared by the FDA for antimicrobial susceptibility testing direct from positive blood culture samples. The solution leverages proprietary molecular identification methods and morphokinetic cellular analysis (MCA) to provide minimum inhibitory concentrations for a range of applicable antibiotics. The fully-automated system is designed to eliminate the lengthy culture and sample preparation steps required prior to antimicrobial susceptibility testing. Recent market studies suggest the solution offers results 1-2 days faster than conventional methods, enabling clinicians to optimize antibiotic selection, dosage, and infusion strategy specific to the individual patient and their infection.

For more information about the company, its products or technology, visit axdx.com .

Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, about our projections as to market need, acceptant and integration of our products. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Information about the risks and uncertainties faced by Accelerate Diagnostics is contained in the section captioned "Risk Factors" in the company's most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 28, 2017, and in any other reports that we file with the Securities and Exchange Commission from time to time. The company's forward-looking statements could be affected by general industry and market conditions. Except as required by federal securities laws, the company undertakes no obligation to update or revise these forward-looking statements to reflect new events, uncertainties or other contingencies.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
BALANCE SHEET
Unaudited
(in thousands)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,609	$ 19,244
Investments	72,609	58,519
Trade accounts receivable	682	34
Inventory	5,720	—
Prepaid expenses	1,157	468
Other current assets	496	183
Total current assets	143,273	78,448
Property and equipment, net	4,844	4,258
Intellectual property, net	140	146
Total assets	$ 148,257	$ 82,852
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,534	$ 992
Accrued liabilities	3,611	3,009
Deferred revenue and income	1,078	35
Total current liabilities	6,223	4,036
Long-term deferred income	—	1,000
Total liabilities	$ 6,223	$ 5,036
Stockholders' equity:		
Common stock, $0.001 par value;		
75,000,000 common shares authorized with 55,291,222 shares issued and outstanding on June 30, 2017 and 75,000,000 authorized with 51,516,309 shares issued and outstanding on December 31, 2016	55	52
Preferred shares, $0.001 par value;		
5,000,000 preferred shares authorized and none outstanding as of June 30, 2017 and December 31, 2016	—	—
Contributed capital	350,577	255,257
Accumulated deficit	(208,601)	(177,289)
Accumulated other comprehensive (loss)	3	(204)
Total stockholders' equity	142,034	77,816
Total liabilities and stockholders' equity	$ 148,257	$ 82,852

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Unaudited
(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Net sales	$ 699	$ 20	$ 1,230	$ 183
Cost of sales	135	—	161	—
Gross Profit	564	20	1,069	183
Costs and expenses:				
Research and development	5,527	8,425	9,815	16,100
Sales, general and administrative	11,460	9,484	21,988	17,144
Total costs and expenses	16,987	17,909	31,803	33,244
Loss from operations	(16,423)	(17,889)	(30,734)	(33,061)
Interest expense and other	(5)	—	(5)	—
Foreign currency exchange loss	(7)	(117)	(33)	(73)
Interest and dividend income	153	140	290	194
Total other income	141	23	252	121
Net loss before income taxes	(16,282)	(17,866)	(30,482)	(32,940)
Provision from income taxes	(175)	—	(175)	—
Net loss	$ (16,457)	$ (17,866)	$ (30,657)	$ (32,940)
Basic and diluted net loss per share	$ (0.31)	$ (0.35)	$ (0.58)	$ (0.64)
Weighted average shares outstanding	53,568	51,213	52,732	51,205
Other comprehensive loss:				
Net loss	$ (16,457)	$ (17,866)	$ (30,657)	$ (32,940)
Net unrealized gain on available-for-sale investments	3	29	3	81
Foreign currency translation adjustment	204	49	204	—
Comprehensive loss	$ (16,250)	$ (17,788)	$ (30,450)	$ (32,859)

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENT OF CASH FLOWS
Unaudited
(in thousands)

	Six Months Ended	
	June 30, 2017	June 30, 2016
Cash flows from operating activities:		
Net loss	$ (30,657)	$ (32,940)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,045	1,147
Amortization of intangible assets	6	5
Amortization of investment discount	219	123
Equity-based compensation	7,450	3,921
Loss on disposal of property & equipment	5	—
(Increase) decrease in assets:		
Accounts receivable	(648)	(92)
Inventory	(5,537)	—
Prepaid expense and other	(624	272
Other current assets	(313)	(1,220)
Increase (decrease) in liabilities:		
Accounts payable	528	(394)
Accrued liabilities	392	1,175
Deferred revenue and income	43	(84)
Net cash used in operating activities	(28,091)	(28,087)
Cash flows from investing activities:		
Purchases of equipment	(1,643)	(2,084)
Purchases of available-for-sale securities	(39,342)	(63,534)
Sales of available-for-sale securities	6,522	1,000
Maturity of available-for-sale securities	18,449	9,380
Net cash used in investing activities	(16,014)	(55,238)
Cash flows from financing activities:		
Issuance of common stock net issuance costs	83,854	—
Exercise of options and warrants	3,418	95
Common stock issuance costs	—	(814)
Payments on capital lease obligations	—	(13)
Recovery of related party short-swing profits	—	991
Net cash provided by financing activities	87,272	259
Effect of exchange rate on cash:	198	—
Increase (decrease) in cash and cash equivalents	43,365	(83,066)
Cash and cash equivalents, beginning of period	19,244	120,585
Cash and cash equivalents, end of period	$ 62,609	$ 37,519

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Accelerate Diagnostics, Inc.

Q2 2017 Earnings Conference Call

August 3, 2017 at 4:15 p.m. Eastern

CORPORATE PARTICIPANTS
Lawrence Mehran, *President and Chief Executive Officer*
Steve Reichling, *Chief Financial Officer*
Laura Pierson, *Investor Relations*

PRESENTATION

Operator
Good afternoon, and welcome to the Accelerate Diagnostics, Inc. ("Accelerate") Q2 2017 Earnings Conference Call. All participants will be in a listen-only mode. Should you need assistance, please signal a conference specialist by pressing the star key followed by zero. After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press star and then 1 using a telephone keypad. To withdraw your questions, you may press star and 2. Please also note today's event is being recorded.

At this time, I'd like to turn the conference call over to Ms. Laura Pierson of Accelerate Diagnostics. Ma'am, you may begin.

Laura Pierson
Before we begin, I would like to advise you that information presented during this conference call may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements include statements about our future and statements that are not historical facts. These statements may contain expectations regarding revenues, earnings, operations, and other results and may include statements of future performance, plans, and objectives. Forward-looking statements include statements pertaining to, among other things, the commercial launch and demand for the Accelerate Pheno ™ system and Accelerate PhenoTest ™ BC kit for positive blood cultures; the potential benefits of our Accelerate Pheno ™ system and the Accelerate PhenoTest ™ BC kit, including accelerated Identification and susceptibility results and estimates of time reduction to results; expectations on placements, sales, and product profitability; the potential of our technology generally; our belief that our expanded manufacturing capability will allow us to meet demand; our expectation of our 2017 performance; and our future development plans and growth strategy, including with respect to research and development as well as product expansion. These statements represent only our belief regarding future events, many of which are inherently uncertain. You are cautioned that any such forward-looking statements are not guarantees of future performance and invoke risk and uncertainties and that actual results may differ materially from those projected in the forward-looking statements as the result of various factors. Information regarding important factors, including specific risk factors that could cause actual results to differ, perhaps materially, from those in our forward-looking statements are contained in reports we file with the SEC. You should read and interpret any forward-looking statement together with the reports we file with the SEC.

I will now turn the conference call over to Mr. Lawrence Mehran, President and CEO of Accelerate. Larry?

Lawrence Mehran
Thank you, Laura, and good afternoon, everyone. It is great to have you with us for our Q2 2017 conference call. We will kick it off with an update on global commercial progress. I will then hand it over to Steve Reichling, our CFO, to review preliminary Q2 financial results. I will then cover our product development progress and conclude with Q&A.

This past quarter was quite exciting as we are seeing continuing momentum in the uptake of the Accelerate Pheno™ system . It was also particularly rewarding for me as I was able to spend considerable time in the field with members of our sales team, visiting hospitals and laboratories in places like Albuquerque, Oklahoma City, St. Louis, Indianapolis, and Detroit. What I learned in the field confirmed three important expectations. One, there is tremendous enthusiasm for the Accelerate Pheno™ system and its potential to drive superior patient outcomes in many institutions. Over and over again I heard, when I was out there, "I want this system." Two, the acquisition process for a new diagnostic device has never been more complicated nor time consuming, extending the sales cycle. And, three, our sales team is doing a great job capitalizing on this interest, while managing these complications, and they are getting better every day.

This is showing up in our numbers. To date, we have signed agreements for 265 instruments. Of these, 220 are evaluation contracts and 45 are placements. For review, we define evaluation contracts as an agreement that allows a customer to evaluate the system with the intent of purchasing if performance meets expectations, while placements are installed, validated, revenue-generating modules whose contracts have converted from evaluations to commercial agreements and for which we can record revenue.

We believe these numbers are quite good and represent a continuation of the strong start we saw in Q1. An important driver of this success is, and will continue to be, our focus on studies, studies that generate abstracts, posters, and journal articles in high impact peer reviewed publications. And in Q2, we saw the first group of what we believe will be a wave of compelling studies conducted using the Accelerate Pheno™ system. These studies further confirm the speed and accuracy of the system, shaving between 35 and 54 hours off the current standard of care, while achieving, we believe, excellent performance in key areas such as sensitivity, specificity, essential and categorical agreement.

Even more compelling were the studies showing the clinical potential of the system. One of these, a retrospective interventional study from Texas Children's Hospital, highlighted the potentially curative power of the system. One of the patients examined was a 15-year-old boy who presented in the ER with rectal bleeding and a fever. A serious infection was suspected, and the patient was admitted, immediately put on broad spectrum antibiotics and blood cultures taken to rule out bacteremia. Eighteen hours later our results would have been available, but given the nature of the study, were not. Twenty-four hours after admittance, the patient's condition worsens. New antibiotics were ordered, but it was too late, and the next day the boy died. Eight hours after he died, ironically, the results from the standard of care, bioMérieux's VITEK ® system, became available. They showed the patient's infection was resistant to the initial treatment and suggested a number of antibiotics that would have been effective but obviously too late. Just imagine if our results had been available. While impossible to know, it is likely this patient would have been immediately shifted to the correct antibiotic with the potential to save his life, and it is data like this that is moving customers through the funnel.

For example, to date in the U.S., we have net evaluation contracts covering 118 instruments and an additional 29 instruments converted into placements. In the EU to date, we have 102 net evaluation contracts and 16 converted into placements. Momentum in both these geographies is building, and now five months into our global launch, we are beginning to see some clear patterns emerge regarding our sales process and timing. These patterns are allowing us to fine tune our funnel map and get a clearer view of our 2017 outlook and beyond.

At the top of the funnel, we are seeing more interest than we anticipated, and, while the contracting process is time consuming and budgets have never been tighter, these customers are moving steadily, if slowly, towards evaluation contracts. Timing here is typically dependent on budget. Accordingly, we have customers who move almost immediately to begin their evaluations, while others delay the start until a new budget cycle. For example, in the U.S., we have seen a significant increase in the number and pace of evaluations in July as some institutions enter a new fiscal year. These evaluations are taking about as much time as anticipated. In the U.S., we expected 90 to 120 days, with the EU being longer. What we are seeing is that in the U.S., this process, largely a verification exercise, is completing in 90 days, the low end of our estimates, with the EU, as mentioned, being longer. In the U.S., moving from evaluation to placement is adding some additional time on top of this, in some cases, up to 90 days, as the final proposals and contracting works its way through the hospitals' purchasing process. Finally, pricing across the board looks good, with AUPs for both consumables and instruments at the high end of our range.

In summary, we are quite excited about our progress to date. The funnel looks strong, and while contracting is going slower than we would like, the significant number of opportunities in the funnel is balancing this out. Accordingly, using this early market data, we remain bullish with our full year outlook looking good, in line with consensus estimates.

I will now hand it over to Steve to review our preliminary second quarter 2017 financial performance.

Steve Reichling
Thank you, Larry, and good afternoon. Revenue for the second quarter was $699,000, and year to date was $1.2 million. This compares to $20,000 and $183,000 from the same respective periods in the prior year. These increases were driven by Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit sales in the U.S. and Europe.

Cost of goods sold was $135,000 in the quarter and $161,000 year to date, resulting in gross margins of 81 percent and 87 percent, respectively. These gross margins are inflated due to instrument inventory sold in the past few quarters that had been previously recorded in Research and Development.

Selling, general, and administrative expenses for the quarter were $11.5 million and $21.9 million year to date as compared to $9.5 million and $17.1 million from the respective same periods in the prior year. These year-over-year increases were driven by higher personnel and customer evaluation-related costs in the U.S. and Europe.

Research and development costs for the quarter were $5.5 million and $9.8 million year to date as compared to $8.4 million and $16.1 million from the respective same periods in the prior year. These year-over-year decreases were due to clinical trial and pre-launch inventory costs incurred in the prior year, which did not repeat in the current year.

Our net loss for the second quarter was $16.5 million and $30.7 million year to date, resulting in a net loss per share of 31 cents and 58 cents on weighted-average basic shares outstanding of 53.6 million and 52.7 million, respectively. These net losses contained $4.2 million and $7.5 million in non-cash stock-based compensation expense.

Net cash used in the quarter excluding proceeds from our recent offering was $11.9 million and $25.7 million year to date. The company ended the quarter with cash and investments of $135.2 million. We anticipate filing the 10-Q for the quarter ended June 30, 2017, on August 7 th .

I will now hand it back to Larry to review our progress in R&D.

Lawrence Mehran
Thank you, Steve. On the research and development front, I wanted to highlight progress we have made on our respiratory kit and discuss our plans for concurrent development. We continue to make steady progress on our respiratory test kit. During the quarter, we completed a 400-sample multi-center pilot study under a protocol that delivers ID&AST results in approximately 10 hours directly from lower respiratory samples. This compares with routine laboratory work-ups which take an estimated 60 or more hours to deliver the same information.

This study, by design, provided early feedback on areas of potential development concern. The most significant challenge identified has already been addressed with an implemented sample preparation improvement. While some development work remains, our continued optimism has been bolstered by our overall external pilot experience. Next steps include final algorithm training and an external performance evaluation for the purposes of achieving a CE mark for our respiratory kit in 2017. Further, we anticipate obtaining FDA clearance in 2018.

The progress we have seen in our respiratory product and the techniques developed during the development process have given us confidence that we are now ready to move into concurrent development on a number of kits simultaneously. Further, we continue to receive requests from our customers for additional kits for sample types such as synovial fluid for joint infections, cerebral spinal fluid for meningitis, peritoneal secretions for peritonitis, along with the previously discussed urine for urosepsis and skin and soft tissue for infections of this tissue. Accordingly, we plan to add two additional development teams over the next quarter, allowing us to work on three kits simultaneously. Details on the specific kits, timelines, and outlook will be provided over the next quarters.

And, with that, I will open it up to questions.

QUESTIONS AND ANSWERS

Operator
And, ladies and gentlemen, at this time, we'll begin the question-and-answer session. To ask a question, you may press star and then 1 using a touchtone telephone. If you are using a speakerphone, we do ask that you please pick up your handset before pressing the keys to ensure the best sound quality. To withdraw your question, you may press star and 2. Once again, that is star and then 1 to ask a question. We'll pause momentarily to assemble the roster.

And our first question today comes from Tycho Peterson from JP Morgan. Please go ahead with your question.

Steve
Hey, guys, it's Steve on for Tycho. Thanks for taking my question, and thanks for all that color around the sales cycle. That was really helpful. Maybe just first, Larry, it's great to hear your takeaways from ASM Microbe. You say there were a lot of presentations on real world use cases, and the clinical statistics seemed pretty compelling, be it percentage of patients where de-escalation was possible, improvements in mortality, et cetera. So as that data continues to roll in, and based on the conversations you've been having, can you talk about which particular stats are the most compelling and what, you know, is helping drive placements, or is it kind of an all-of-the-above type situation?

Lawrence Mehran
Yes, Steve, thanks for the question. Yeah, clearly, at ASM Microbe, we were excited about what we did there. Our investigators, using the Accelerate Pheno™ system, were able to generate tremendous results. Like you alluded to, in a number of cases, we saw, for example, at Wash U, we saw that almost 70 percent of the patients that the Accelerate Pheno™ system would have been used on would have had their therapy changed. This is a remarkable statistic, and this was duplicated in a number of other institutions, including Texas Children's Hospital, which we highlighted earlier in the conference call.

These kinds of significant clinical changes are what is really driving our customers through the funnel, and I think it— it is those studies that are making a real difference. I mean, at the end of the day, clinical outcomes matter, and those clinical outcomes like we're seeing, those excellent clinical outcomes, are driving really positive economic benefit, and our customers are excited about that, and it's driving more people into the funnel and allowing those folks to move to evals and those evals to convert.

Steve
Got it. And then can you provide any additional color on your initial commercial experience in the U.S.? How many systems is the typical hospital purchasing, and what's the percentage of placements that are being [audio cut out] capital versus range and rental basis?

Lawrence Mehran
Yeah, sure. I'll take the second part of that question first. The majority in the U.S. are capital. As we've said, the sales mix thus far supports the assumption. It looks like 22 of 29 in the U.S. have been capital, and 7 out of the 29 were rental. In the EU, it's exactly the opposite. Two out of 10 have been capital, and 8 out of 10 have been rentals.

And then related to the first part of your question, Steve, we're typically seeing — and, as we've discussed prior, that the average site requires two to three modules. What we've actually seen is that folks are tending toward the higher end of that range, you know, more towards the three on average, with many customers at four modules.

Steve
Got it. And then just lastly on respiratory, it sounds like you're making good progress there. Once you start commercializing that cartridge and ramping up manufacturing, are you going to have to invest in a new line, or can you leverage your existing manufacturing footprint? Thanks.

Lawrence Mehran
Yeah, we can leverage our existing manufacturing footprint, Steve.

Steve
Got it. That's all for me. Thanks, guys.

Lawrence Mehran
Thank you.

Operator
Our next question comes from Bill Quirk from Piper Jaffray. Please go ahead with your question.

Bill Quirk
Great. Thanks. Good afternoon, everybody. I guess the first question, and I realize we're still pretty early in the overall launch, but, Larry, any sense for how many of those folks who are in the evaluation process are expected to cross the finish line into a revenue-generating placement?

Lawrence Mehran
Yeah, I mean, good question, Bill. I would say the vast majority of them are. To get into our evaluation program is quite arduous. Our salespeople are required to execute a contract which, in essence, requires folks if certain end points are met, to acquire the system, in general, all of these evals have identified capital or another method of purchasing. It's all lined up for them to convert to a commercial contract. Further, so far, we have not lost any evals due to unsuccessful system performance, we're quite pleased about that. I think, in general, people have been quite pleased with what they're seeing, and we expect the vast majority to go across the finish line.

Bill Quirk
Got it. Okay. And thinking — I guess, pivoting, rather, to the lower respiratory pipeline product, good to hear that you're obviously endorsing the existing timelines for that. Given where we are in that development, Larry, would it be safe to assume that you'll probably be entering into the U.S. clinical trials probably in the, call it, the fall, early — you know, call it late fall? Is that a reasonable time to assume?

Lawrence Mehran
No, Bill, I think it will be the first part of next year.

Bill Quirk
Okay. Okay, understood. And then the sample types, are you going to include both BALs as well as trach aspirates in that product?

Lawrence Mehran
That's what we're targeting, yes.

Bill Quirk
Fantastic. And then the last question for me is just about the additional two R&D teams. Obviously, glad to hear that this is being demand-driven from your customer base, they want to see more sample types out faster from Accelerate. But, obviously, you know, it does present a management challenge from your end in terms of managing the three projects, the three teams, making sure that everybody is obviously staying up to speed. Could you just talk a little bit about the potential for kind of R&D distraction, if you will?

Lawrence Mehran
Yeah, Bill, I think it's a good question, and I'll tell you, we could not have done this effectively a couple of years ago; however, we now are at a point where we have significant management bandwidth and feel not only comfortable with the demand from the customer and our technical capabilities but also our capabilities — or our organization's capabilities of dealing with this type of concurrent development. In essence, we will be taking some of our top team leaders and moving them into this development arena, they're really already to go, and while it's a bit of a reshuffling, I think, you know, we feel quite comfortable with it.

Bill Quirk
Got it. Thanks, guys.

Lawrence Mehran
Thank you.

Steve Reichling
Thanks, Bill.

Operator
Our next question comes from Brian Weinstein from William Blair. Please go ahead with your question.

Brian Weinstein
Hey, guys, thanks for taking the questions. Just starting out with a utilization question, of those that were early users of this, how are you seeing them utilize the system in clinical practice? What type of patients are they seeing, and what — is there a consensus that's starting to be driven on this?

Lawrence Mehran
Yeah, it's still early days, and it's difficult to project, but of the customers that are actively running clinically, we haven't seen a triage at all, they're running everything that they've got. As I mentioned before, I do think it's a possibility that in this next wave of conversions — and it's going to be a very significant wave — you'll see some of those folks only running gram-negative. But the first adopters are running everything.

Brian Weinstein
Okay. Thank you for that. Did you mention — I might have missed it — anything about adding resistance markers to the blood culture kit? Where does that project stand at this point?

Lawrence Mehran
Yeah, it's— it's still on track, and we expect to have that development on — this year.

Brian Weinstein
Development done, meaning submit something to the FDA or be on the market with it?

Lawrence Mehran
No, we'll be — I think we will be on the market with it in Europe. I think it's unlikely that it will be approved for use in the U.S. this year.

Brian Weinstein
Got it. And then are there any steps that you guys can take, or what have you learned about how you can accelerate that process of closing these accounts or getting them through these hospital capital cycles? Is there anything that you guys can particularly do, or are you really just sort of at the mercy of the individual system?

Lawrence Mehran
You know, look, Brian, we're very cognizant of the need to drive revenue, and our teams are doing everything that they can. The majority of our conversions, however, are not yet live, not due to anything structural, but a number of these that have converted acquired prior to verification, while they purchased the system, they're still verifying or they have — you know, they're still building interfaces into their LIS, for example. those are the kind of things that we're likely to see, and I think we'll get better, it will get more streamlined over time, but I don't think that there's any issues that we're seeing that we need to tackle right now.

Brian Weinstein
Okay, and then the last one for me, I just wanted to confirm that I heard you correct, Steve. Did you guys say that you were comfortable with the revenue consensus, or was that the instrument number of placements that you guys track as far as what the analysts are looking for? And can you just be more specific about what those consensus numbers are?

Lawrence Mehran
Yeah, I mean, I — Steve, do you want to take that, or do you —

Steve Reichling
Yeah. Well, I think we certainly feel comfortable about the placements for the full year consensus across our four analysts as well as the revenue figure.

Brian Weinstein
Okay. Thanks.

Operator
And, ladies and gentlemen, we have reached the end of the Q&A session. At this point, I'd like to turn the conference call back over to management for any closing remarks

CONCLUSION

Lawrence Mehran
Well, thank you, everyone, for the time today and the questions. In closing, I'd say we made excellent progress this quarter on our three areas of focus for 2017, which are, first, to achieve a great launch of the Accelerate Pheno™ system ; second, to maintain product superiority through targeted product improvements; and, third, to develop additional tests for use on the platform.

I continue to be excited by our company, its first platform, and the tremendous potential of both. And thanks to all our collaborators, our tremendously hard working employees, customers, and of course investors, who are making it possible to build this great lifesaving business. Look, it's a battle, folks, but it's a battle we're going to win. Thank you.

Operator
Ladies and gentlemen, with that, we will conclude today's conference call. We do thank you for joining. You may now disconnect your lines.