ACCELERATE DIAGNOSTICS, INC

FORM 8-K
(Current report filing)

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Address	3950 S. COUNTRY CLUB ROAD #470 BUILDING 3-307 TUCSON, AZ, 85714
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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) **November 2, 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 November 2, 2017, Accelerate Diagnostics, Inc. issued a press release announcing its preliminary financial results of operations for the quarter ending September 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 November 2, 2017
99.2	Preliminary Earnings Call Transcript, November 2, 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: November 6, 2017

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated November 2, 2017
99.2	Preliminary Earnings Call Transcript, November 2, 2017

Exhibit 99.1

Accelerate Diagnostics reports Q3 2017 financial results

TUCSON, Ariz., Nov. 02, 2017 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. today announced preliminary financial results for the quarter ending September 30, 2017. The company further reported signed agreements for 295 instruments year to date; contracts for customer evaluations total 239 instruments while revenue generating placements grew to 56 across the U.S., European, and Middle East regions.

Net sales for the third quarter 2017 was $828,000 compared to $24,000 in the third quarter of 2016. The increase was driven by sales of the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

"Eight months into our launch, we are meeting or exceeding the majority of our expected commercial metrics and funnel assumptions," said Lawrence Mehren, President and CEO. "While we would prefer the rate of conversions to be faster, we believe the number of qualified prospects and evaluation contracts, conversion win rate, pricing, and other measures confirm the value of the company and its products."

The company also reported achieving several milestones across a number of development initiatives during the quarter, highlighting the completion of the assay development phase for its upcoming kit targeting severe pneumonia. Development is also complete for two new key antibiotics for European customers that will be added to the Accelerate PhenoTest™ BC kit and submitted for CE Mark near year end. In addition, the company announced plans to develop new kits aimed at sample types for complicated urinary tract infections and intra-abdominal infections.

"Complicated urinary tract infections are a great target for us," said Dr. Romney Humphries, Chief Science Officer for Accelerate. "Often these organisms are multi-drug resistant, cost an estimated $14 billion in the United States, and may lead to urosepsis, a potentially fatal condition."

Intra-abdominal infections also represent a high-acuity target for the fast, phenotypic, and fully automated antimicrobial susceptibility results offered by the company's system, Humphries said, noting that these infections often keep patients in the hospital for a week or longer when associated with highly drug-resistant organisms which can cause typical empiric therapy to fail.

President and Chief Executive Officer, Lawrence Mehren, and Chief Financial Officer, Steve Reichling, will host a conference call to review the financial results, commercial progress, and development updates at 4:15 p.m. Eastern Time on November 2, 2017.

Preliminary third quarter 2017 results

- Net sales of $828,000 compared to $24,000 in the third quarter of 2016
- Gross margin realized was 77% including inventory previously recorded as research and development (R&D) expense

- Selling, general, and administrative expenses of $11.6 million, compared to $9.6 million in the prior year period, driven by higher personnel and customer evaluation-related costs across the U.S. and Europe

- R&D expenses for the third quarter of $6.4 million, compared to $7.9 million in the same quarter of 2016 due to clinical trial and pre-launch inventory costs incurred in the prior year period which did not repeat

- Net loss of $17 million, or $0.31 per share on weighted average basic shares of 55.3 million shares outstanding, which includes $3.5 million in non-cash stock-based compensation expense

- Net cash used in the quarter was $13.9 million, ending the quarter with total cash, and cash-equivalents from all activities of $121.3 million

Full financial results for the quarter ending September 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 November 7 th . Investors are cautioned not to place undue reliance on these preliminary estimates in the event of material changes.

Audio Webcast and Conference Call

Listen to an audio webcast of the call by visiting the events section of the company's investor relations website at ir.axdx.com. A replay of the audio webcast will be available until November 16, 2017.

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 3435682.

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 10112771 until November 16, 2017.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. (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 recently obtained FDA marketing authorization for antimicrobial susceptibility testing direct from positive blood culture samples using its Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit. The system and kit leverage 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.

The "ACCELERATE DIAGNOSTICS" and "ACCELERATE PHENO" and "ACCELERATE PHENOTEST" logos and marks are trademarks or registered trademarks of Accelerate Diagnostics, Inc.

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 when certain key business milestones may be achieved, such as the ongoing commercial launch, demand, and potential of our products or technology, the growth of the market, our estimates as to the size of our market opportunity and potential pricing, our competitive position and estimates of time reduction to results, and our future development plans and growth strategy. 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)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,431	$ 19,244
Investments	86,889	58,519
Trade accounts receivable	1,111	34
Inventory	7,341	—
Prepaid expenses	1,048	468
Other current assets	460	183
Total current assets	131,280	78,448
Property and equipment, net	4,690	4,258
Intellectual property, net	137	146
Total assets	$ 136,107	$ 82,852
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,369	$ 992
Accrued liabilities	3,733	3,009
Deferred revenue and income	1,081	35
Total current liabilities	6,183	4,036
Long-term deferred income	—	1,000
Total liabilities	$ 6,183	$ 5,036
Stockholders' equity:		
Common stock, $0.001 par value;		
75,000,000 common shares authorized with 55,397,563 shares issued and outstanding on September 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 September 30, 2017 and December 31, 2016	—	—
Contributed capital	355,458	255,257
Accumulated deficit	(225,676)	(177,289)
Accumulated other comprehensive (loss)	87	(204)
Total stockholders' equity	129,924	77,816
Total liabilities and stockholders' equity	$ 136,107	$ 82,852

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

	Three Months Ended		Nine Months Ended	
	September 30, 2017	**September 30, 2016**	**September 30, 2017**	**September 30, 2016**
Net sales	$ 828	$ 24	$ 2,058	$ 207
Cost of sales	191	—	352	—
Gross Profit	637	24	1,706	207
Costs and expenses:				
Research and development	6,351	7,874	16,166	23,974
Sales, general and administrative	11,601	9,566	33,589	26,710
Total costs and expenses	17,952	17,440	49,755	50,684
Loss from operations	(17,315)	(17,416)	(48,049)	(50,477)
Interest expense and other	2	—	(3)	—
Foreign currency exchange loss	(40)	(42)	(73)	(115)
Interest and dividend income	323	159	612	353
Total other income	285	117	536	238
Net loss before income taxes	(17,030)	(17,299)	(47,513)	(50,239)
Provision from income taxes	(45)	—	(220)	—
Net loss	$ (17,075)	$ (17,299)	$ (47,733)	$ (50,239)
Basic and diluted net loss per share	$ (0.31)	$ (0.34)	$ (0.89)	$ (0.98)
Weighted average shares outstanding	55,316	51,239	53,603	51,216
Other comprehensive loss:				
Net loss	$ (17,075)	$ (17,299)	$ (47,733)	$ (52,239)
Net unrealized gain on available-for-sale investments	(7)	(70)	(4)	11
Foreign currency translation adjustment	91	(8)	295	(8)
Comprehensive loss	$ (16,991)	$ (17,377)	$ (47,442)	$ (50,236)

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

	Nine Months Ended	
	September 30, 2017	**September 30, 2016**
Cash flows from operating activities:		
Net loss	$ (47,733)	$ (50,239)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,595	1,745
Amortization of intangible assets	9	8
Amortization of investment discount	298	251
Equity-based compensation	10,970	6,591
Realized (gain) on sale of investments	—	(6)
Loss on disposal of property & equipment	3	—
(Increase) decrease in assets:		
Accounts receivable	(1,077)	(82)
Inventory	(7,079)	—
Prepaid expense and other	(392)	525
Other current assets	(277)	(90)
Increase (decrease) in liabilities:		
Accounts payable	359	103
Accrued liabilities	780	670
Deferred revenue and income	46	(83)
Net cash used in operating activities	(42,498)	(40,607)
Cash flows from investing activities:		
Purchases of equipment	(2,055)	(2,301)
Purchases of available-for-sale securities	(68,423)	(73,585)
Sales of available-for-sale securities	9,522	8,716
Maturity of available-for-sale securities	30,049	14,955
Net cash used in investing activities	(30,907)	(52,215)
Cash flows from financing activities:		
Issuance of common stock net issuance costs	83,741	80
Exercise of options and warrants	4,562	864
Common stock issuance costs	—	(814)
Payments on capital lease obligations	—	(13)
Recovery of related party short-swing profits	—	866
Net cash provided by financing activities	88,303	983
Effect of exchange rate on cash:	289	(15)
Increase (decrease) in cash and cash equivalents	15,187	(91,854)
Cash and cash equivalents, beginning of period	19,244	120,585
Cash and cash equivalents, end of period	$ 34,431	$ 28,731

Investors May Contact:

Laura Pierson, Accelerate Diagnostics, +1 520 365-3100, investors@axdx.com

Reporters May Contact:

Andrew Chasteen, Accelerate Diagnostics, +1 520 365-3100, achasteen@axdx.com

Accelerate Diagnostics, Inc.

2017 Q3 Results Conference Call

Thursday, November 02, 2017, 4:15 PM Eastern

CORPORATE PARTICIPANTS

Lawrence Mehren - *President, Chief Executive Officer*

Steve Reichling - *Chief Financial Officer*

Laura Pierson - *Investor Relations*

PRESENTATION

Operator
Good day and welcome to the Accelerate Diagnostics, Inc. 2017 Q3 Results Conference Call. All participants will be in a listen-only mode. After today's presentation, there will be a question and answer session. Please note this event is being recorded.

I would now like to turn the conference call over to Laura Pierson of Accelerate Diagnostics. Please go ahead.

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 includes 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 the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit, including Accelerate 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 and 2018 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 involve risk and uncertainties, and that actual results may differ materially from those projected in the forward-looking statements as a 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 Mehren, President and CEO of Accelerate. Larry…

Lawrence Mehren
Thank you, Laura, and good afternoon, everyone. I am happy to have you with us for our Q3 2017 conference call. We will begin this call as usual with an update on global commercial progress. During the section, I will also discuss our sales funnel, some of our model assumptions and a forecast for the rest of the year and into 2018. I will then hand it over to Steve Reichling, our CFO, to review preliminary Q3 financial results. I will then cover our product development progress and conclude with Q&A.

This quarter's commercial progress was very exciting. Year-to-date, we are meeting or exceeding the majority of our expected commercial metrics and final assumptions while dissecting time consuming elements of the hospital acquisition process and refining our sales approach.

At the top of the funnel, overall interest continues to build for the Accelerate Pheno™ system in the US and the EU. Market awareness is growing, enquiries increasing and our funnel of interested qualified prospects that we plan to move to a valuation contract is large and expanding.

For example, in North America alone, this group of qualified prospects now totals over 600 accounts representing approximately 1,800 instruments. Further, these qualified prospects are turning into active customers although not yet reflected in our reported revenues; we are enjoying a strong commercial launch of the Accelerate Pheno™ system as measured by new accounts acquired.

To-date we have signed agreements for 295 instruments. Of these, 239 are under evaluation contracts and 56 are placements. For review we define evaluation contracts as an agreement which allows a customer to evaluate this system with the intent of purchasing if performance meets expectations. We define placements as installed, validated revenue generating instruments whose contracts have converted from evaluations to commercial agreements and for which we can record revenue.

And while we would prefer the rate of these conversions to be faster, we believe the significant majority will convert to placements. Currently, evaluation contract conversion to placements is above our expectations, remaining close to 100%. For example, in all of North America we have lost only one evaluation. In this particular account, our analytical performance was excellent. However, a major staff reorganization in a lab resulted in a shift in acquisition priorities.

We also believe our support is broad based with qualified prospects, evaluation contracts and placements coming from across all market segments from large centralized labs to small regional hospitals. We believe that this is an affirmation that the Accelerate Pheno™ system platform is highly attractive across the potential spectrum of labs we expect for full penetration of the market. Moreover, we believe this market is also larger than we originally estimated.

Having now prospected a large segment of the potential customers in the US, collecting data as we went along, we now believe that the sepsis market is 20% larger than we originally calculated with a total opportunity of approximately 2.3 million tests. We think this combined with our panels for respiratory and other indications such as urinary tract infections and intra abdominal infections makes our market opportunity appreciably larger and quite attractive.

Pricing is solid for both instruments and reagents. For example, in both the US and the EU, reagent pricing on average remains above $200 for all our clinical customers. Globally, instrument mix is also favorable to our model, with more than 50% of deals closed this year for capital.

Reagent pull through or annuity per box is also something we're tracking closely. And while it is early, what we are seeing with our first customers is encouraging. Not only are these customers exceeding our expectations for the total number of kits they are purchasing, they are also purchasing more instruments than we expected. So while annuity per instrument is in line with our expectations, annuity per customer is exceeding our expectations.

For example, our contract with one of our new customers calls for them to purchase 120 kits per month. They could have consumed these kits running twice a day on two instruments, but instead have chosen to purchase a third instrument to ensure constant availability for patient cases. We believe this is a positive development and one we are seeing with other customers as well. And while it is still very early, this is resulting in annuity per box ranging from 0.34 to 1.71 kits per instrument per day.

Finally, we believe clinical performance has been outstanding, with numerous papers moving towards publication or already having been accepted. Most notably, our data from the US clinical trial has been submitted and accepted by the Journal of Clinical Microbiology. In addition to this important publication, our investigators have so far this year published three papers, submitted another four that are awaiting decision, with four more in process. We believe that this, combined with 28 poster presentations, highlighting the significant benefits of the Accelerate Pheno™ system, are helping to drive the high degree of interest we are seeing in the platform.

More importantly, the number of significant clinical interventions our customers are reporting is exciting and we believe speak to the significant clinical utility of the system. For example, a customer in the UK found that, of their last 105 patients run on the Accelerate Pheno™ system, 85 of those runs resulted in meaningful interventions, including among others escalation, de-escalation and isolation. We believe that results like this spread by word-of-mouth and in papers and posters will continue to drive broad based adoption of the platform.

Reason for optimism for sure, however, as mentioned in our Q2 call, the acquisition process for new diagnostic device has never been more complicated nor time consuming, extending the sales cycle. We highlighted in the last call that the period to complete the verification, signing the contract and moving to a placement, originally estimated at three to four months could extend an additional three months as our customers take longer to work through the contracting process. With more contracts under our belt, we believe that most of the evaluation contracts in the funnel for 2017 close will take this amount of time to convert to placements.

In addition, as we move to placements in more sites, we are seeing an additional time period post-contract signing as sites build a unique LIS interface into our system. This is typically an internal effort by the hospital's IT group coordinating with an outside LIS vendor.

Our current experience suggests that this is adding an additional three months post-contract signing until we begin to generate meaningful reagent revenue. We have been all over these unexpected increases to our sales cycle, dissecting the acquisition process step-by-step and refining our approach.

We have now developed mitigations for both of these time increases, and believe these will have a meaningful impact. For example, simply increasing the number of instruments used in the verification can significantly decrease the time to completion at little cost to Accelerate. Changes like these, we believe will decrease time to reagent revenue for 2018, bringing it back more in line with our expectations. However, for 2017, we expect this to reduce reagent sales.

In summary, eight months into our launch, we have met or exceeded our expectations on most of our key perimeters, including the number of qualified prospects, the number of evaluation contracts, conversion percentage, pricing for tests and instruments, capital mix and annuity per customer.

However, we underestimated the time that it would take for a customer to convert from an evaluation contract to a placement and to meaningful reagent revenue. We believe this will result in lower sales in the short term due to a decrease in reagent revenue for the year.

In addition, we currently have 40 contracts for placements under review with an expected close in 2017. However, there is risk that some of these could get pushed into Q1, 2018. Given this, we expect to finish the year with revenues in a range of $5 million to $8 million.

We expect the success we have achieved in signing evaluation agreements and converting them to placements will show-up in reported revenues in 2018. Hence, we expect to show strong growth in 2018 with revenue growth between five and seven times 2017.

And with that, I'll turn it over to Steve Reichling to review our Q3, preliminary results. Steve.

Steve Reichling
Thank you, Larry and good afternoon. Revenue for the third quarter was $828,000 and $2.1 million year-to-date compared with $24,000 and $207,000 for the same period in the prior year. These increases were driven by sales of the Accelerate Pheno system and Accelerate PhenoTest™ BC kit across the US, Europe and now the Middle East.

Cost of goods for the quarter were $191,000 and $352,000 year-to-date resulting in gross margins of 77% and 83% respectively. These gross margins are inflated due to instrument inventory sold in the past few quarters that were previously recorded to research and development expense.

Selling, general and administrative expenses for Q3, 2017 were $11.6 million and $33.6 million year-to-date compared with $9.6 million and $26.7 million for the same period of 2016. These year-over-year increases were driven by higher personnel and evaluation related costs in the US and Europe.

Research and development costs for the quarter were $6.4 million and $16.2 million year-to-date compared to $7.9 million and $24 million from the same period in the prior year. This year-over-year decreases were due to clinical trial and prelaunch inventory costs incurred in 2016 that did not repeat in the current year.

Our net loss for the third quarter was $17 million and $47.7 million year-to-date resulting in a net loss per share of $0.31 and $0.89 on weighted average basic shares outstanding of 55.3 million and 53.6 million respectively. These net losses contained $3.5 million and $11 million year to date in non-cash stock base compensation expense.

Net cash used for the quarter was $13.9 million and $40.2 million year to date. The company ended the quarter with cash and investments of $121.3 million.

We anticipate filing the 10Q for the quarter ended September 30 th, 2017 on November 7 th, 2017. I will now hand it back to Larry to review our R&D progress.

Lawrence Mehren
Thank you, Steve. So this quarter, the team achieved several milestones across a number of development initiatives that are focused on three key strategies. First, unlocking future test volume through new kits and expanded claims. Second, improving existing product performance and the experience of our customers and third, inventing new technologies that make life-saving decisions easier for clinicians and safer for patients facing serious infections.

Let us start with respiratory. This week marks the completion of assay development activities for kit targeting severe pneumonia. Over the coming weeks, we plan to kick-off verification and the performance evaluation study to achieve a CE mark before the end of the year or just after the holidays. For the US clinical trial for respiratory, we plan on including a clinical arm to demonstrate the clinical and health economic benefits of the device.

Further, we plan on expanding the indication to include severe community acquired bacterial pneumonia for which we will add two additional probes and a novel sample prep device. We plan to begin site recruitment in the next few weeks and plan to begin the trial in Q2 2018. While our focus is on respiratory, the team also completed market assessments and collective customer requirements for the next kits aimed at sample types for acute urinary tract infections and intra-abdominal infections.

We believe these can be developed concurrently and are in the process of building out the teams behind them. Urinary tract infections are a great target for us. More than 7.5 million emergency department visits are associated with UTIs. Of patients admitted, more than 500,000 in-patients principal diagnosis is a Urinary Tract Infection ("UTI"), meaning the primary reason for their hospital stay is due to UTI. On average, these patients are in the hospital for four days and cost for serious Urinary Tract Infections is over $13 billion annually in the United States alone.

Often, these organisms are multi-drug resistant and may lead to urosepsis, a potentially fatal condition. We believe rapid susceptibility testing will aid treating physicians on optimal therapy choices.

Intra-abdominal infections also represent a high-acuity target for the Accelerate Pheno™ system solution. More than 200,000 inpatients are diagnosed with an intra-abdominal infection each year. These patients are often quite sick in the hospital for nearly seven days. These infections are difficult to diagnose given the polymicrobic nature of the sample and are often associated with drug resistant organisms where empiric therapy may fail. Again, we believe rapid identification and susceptibility testing will aid treating physicians on optimal therapy choices.

For blood culture, we completed development of two new antibiotics for Europe; amoxicillin, clavulanic acid and cephalexin. These drugs are both key to de-escalation or limiting exposure to unnecessary antibiotics for the EU. In addition, based on customer feedback, we have expanded the organism converts of three existing antibiotics in the blood culture kit, adding 22 new assays **.** We plan to achieve a CE mark for these additions before end of year. In addition to menu expansion for Europe, efforts to reduce signal noise and other updates have improved re-portability for identification to around 98%, consistent with best-in-class molecular diagnostics.

Finally, we completed feasibility for a new method to improve sample cleaning and concentration which we have mentioned previously. Based on early data, we believe this new method will reduce supply risk, improve logistics by likely eliminating cold shipments and offer a margin benefit to the current and future kits.

At this time, we will turn it over to the operator for questions.

QUESTION AND ANSWER

Operator
Thank you. We will now begin the question and answer session and the first question comes from Bill Quirk with Piper Jaffray. Please go ahead.

Bill Quirk
Thanks. Good afternoon, everybody. First question Larry, just help us a little bit about how the reps are spending their time. Are you seeing any shift here in the third quarter from prospecting to working with their validation placements, to try to get them across the finish line, just trying to understand kind of what the mix is there?

Lawrence Mehren
Yes, Bill. Thanks for the question. It is seasonal and at the end of the year you are going to see our reps do a lot more work converting the evaluations that they already have put in place to placements and that's what you are seeing in the latter part of the third and in the fourth quarter.

Bill Quirk
Okay. Got it. And then just thinking about the 2017 guidance, obviously it suggest pretty nice step-up here in the fourth quarter. Does that mean, and I suppose somewhat in conjunction with your previous answer, that you are pretty optimistic about nearing the finish line on the number of these validation placements?

Lawrence Mehren
That's correct, Bill. We have, as we mentioned 40 contracts right now that are marked for close in Q4 of 2017, and we feel optimistic about those. So we think it looks really good.

Bill Quirk
Okay. Excellent. And then, last one from me, is the comment about, you are seeing faster validations when you have additional units onsite. And so, can you just elaborate on that a little bit? Are you suggesting that Accelerate is placing some additional units at no cost or you are giving them loaner units or you are encouraging them to take more modules? I am just trying to kind of understand some of the dynamics around that. Thanks.

Lawrence Mehren
Sure, Bill. The context for that was a mitigation to increase or rather decrease the time for validation. And, yes, the validation is a fixed number of samples. So the more units, more instruments you have, the faster that goes. And so, for those that have four, five, six modules, the validation can go quite quickly, but those that have two, it's slower. In the future, we will loan those customers extra units to complete their validation much more quickly.

Bill Quirk
Okay. Got it. Thanks guys.

Operator
Our next question comes from Tycho Peterson with JP Morgan. Please go ahead.

Steve Reiman
Hi, guys. It is Steve Reiman on for Tycho. Thanks for taking my question. Larry, let me start, can you talk a little bit more about how the evaluation contracts are structured. Are there set timelines within the contracts by which the customer has to validate the system within a certain time period? And then if the system hits all the performance targets, our customers contractually obligated to purchase the system or they still have an opportunity to decide whether or not they want to take it on?

Lawrence Mehren
So first there is a period in the contracts Steve, typically a 120 days. And in terms of whether the contract is binding, I would say, in general, the contract does require them to purchase, but we expect to go through a second contracting process and go through a lot of [indiscernible] before it turns into a placement.

Steve Reiman
Got it. And then, recognizing it's really early, but can you give any color on, what you are seeing in terms of the use case of the Accelerate Pheno™ System in the field, are you seeing it used primarily in gram-negative, pediatrics or just kind of across the board in all sepsis cases?

Lawrence Mehren
Yes, for initial customers, we haven't seen a bias towards, a gram-positive, or gram-negative. We have heard from some of our directors that they [initial customers] might consider focusing their Acclerate Pheno™ system volume on gram-negatives for cost reasons, but as we've said before bifurcating the workflow between gram-positive and gram-negative bacteria to us doesn't make sense. While there'll be a small savings in direct cost. The overall operational challenges posed by that makes it unlikely for most customers.

Further, our Chief Scientific Officer reminded me recently that the situation for gram-positive is evolving rapidly, and that it's not just a question of MRSA versus MSSA any longer. There is a number of bad bugs out there and Accelerate Pheno™ system susceptibility analysis is required to address these…these emerging challenges. So for example, our first customers are really running everything that they have on the Accelerate Pheno™ system.

Steve Reiman
Got it. And I appreciate all the color on the LIS component post install, is there anything…any enhancements you can make to the systems that streamline that process be it through a system upgrade or software upgrade to kind of shorten up that time period that takes to make the LIS upgrade on the hospital end?

Lawrence Mehren
So Steve the answer is, yes. After we have covered interfaces for all the major LIS vendors, the speed at which we can accomplish that increases significantly. Further, right now we do the LIS interface concurrent…consecutively post the sight going live. We believe that we can make this a concurrent process, while they are in their verification phase which should allow us to decrease the time even further.

Steve Reiman
Got it. And lastly, and apologies if I missed this, but would you be able to give the split between US and EU for the customer evaluation, just how many of those are Europe versus US?

Lawrence Mehren
Yes, so of the evaluation contracts, 139 of those are in the US and 100 are in the EU.

Steve Reiman
Got it. That's all from me, thanks, guys.

Lawrence Mehren
Thank you.

Operator
Again, if you have a question please press "*" then "1." Our next question comes from Brian Weinstein with William Blair. Please go ahead.

Brian Weinstein
Hey, guys. Thanks for taking the question. So let's start kind of in the frontend of the process here in getting an evaluation started. Last quarter, I think you guys had 220 evaluations, now you are saying that you have I think 239 is the number there. So, you increased that by 19, maybe, I thought that could be a little bit stronger. Are there additional headwinds towards even getting an eval started at this point, I think we have spent most of the time on the call talking about you know, once an eval is going…getting that placement into revenue, but can you talk about kind of on the front end what's going on and maybe slowing down in the pace of initial just evals kicking off?

Lawrence Mehren
Yes, sure Brian. So, I think mathematically what you said is correct. I would say however, the delta is not as significant as the numbers would suggest because some customers have decided to go directly to acquisition skipping the evaluation process entirely. For example, I know at least four customers, I think it's around 13 instruments, who are proceeding directly to acquisition. So, I think this is a positive trend. Further, as I mentioned to Bill earlier, there is some seasonality to PVP and conversion to placement. And so, we expect to see more PVPs in the first half of the year than the second half.

Brian Weinstein
Okay. And then, you talked about…I want to make sure I heard these numbers correct, that you had qualified prospects of over 600, if let's say you had not signed up another qualified prospect, if that stopped right now today, when would those 600, how long would it take those 600 to work themselves completely through the funnel to the point that you think that they would be revenue generating on the commercial side?

Lawrence Mehren
So, Brian, let me walk you through the sales cycle, I think that might be helpful. So, let's begin with the established, with establishing of a qualified account. So, as we mentioned, we have over 600 of these currently in the funnel and while its variable, some…I would say some qualified accounts moved directly to evaluation, others take a bit longer. And so, for example, I would say we expect about one in four to move directly to an evaluation. And once an evaluation has been requested, we begin the contracting and installation process. This typically takes between one and three months. Once that's completed, once installed, the evaluation typically takes between three and four months to complete and then post the successful completion of the evaluation, contract conversation to placement is taking an additional three months as we mentioned in the call. And then, finally, upon execution of the placement our contract hospital…the hospital IT staff builds an LIS interface to the Accelerate Pheno™ system and the site becomes what we call active, and this is taking about two to three months.

And I would also say again, while this represents our current experience, we have already undertaken a number of programs to significantly reduce the additional time at each of these key steps. For example, as we mentioned in our remarks, we believe simply increasing the number of months…instruments used for accounts evaluation will decrease the time significantly by increasing throughput.

Brian Weinstein
Okay. That was helpful to dig into that. Last one from me, is there anything in terms of large tenders that are taking place outside the US that you are guys competing for and how meaningful can those be. Can you give us an update if there are any tenders that are going on about the timing for those? Thanks.

Lawrence Mehren
Yes, sure, Brian. There are a number of tenders ongoing in the EU, some of them are meaningful, particularly in France. And I can't tell you exactly what the timing for those is today. I would also say that there are a number of meaningful accounts that we are working in the US which beyond the 40 contracts that we talked about in Q4 of 2017 could hit in the early part of 2018?

Brian Weinstein
Thank you.

Operator
This concludes our question and answer session. I would like to turn the conference back over to Mr. Lawrence Mehren for any closing remarks.

CONCLUSION

Lawrence Mehren
So, thank you. And in closing, I would like to say thanks to all the Accelerators out there. Your inventive minds, open hearts and steel wills are an inspiration to all. And then, to our shareholders, without you none of this would be possible. Thank you very much. Together we are changing the practice of medicine. And this quarter, confirm that we got it nearly all right. We have the right product generating high demand and good prices. And while the sales cycle is longer than we expected, we are confident that we are addressing this. And this confidence, I will tell you is not hubris; rather it comes from working with the team that has faced much more significant roadblocks, and has always knocked them down. We expect this to continue. Thanks.

Operator
The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.