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) **February 23, 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))

Item 2.02 Results of Operations and Financial Condition.

On February 27, 2017, Accelerate Diagnostics, Inc. (the "Company") hosted a conference call to discuss its preliminary results of operations for the quarter and fiscal year ended December 31, 2016. A copy of the transcript of the conference call is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 for Form 8-K, the information in this Item 2.02, including Exhibit 99.1, 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 8.01. Other Events.

On February 23, 2017, the Company issued a press release announcing the U.S. Food and Drug Administration granted the Company's *de novo* request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for identification and antibiotic susceptibility testing of pathogens directly from positive blood culture samples. A copy of the Company's press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference in its entirety.

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	Preliminary Earnings Call Transcript, February 27, 2017
99.2	Press Release, dated February 23, 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: March 1, 2017

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Preliminary Earnings Call Transcript, February 27, 2017
99.2	Press Release, dated February 23, 2017

Accelerate Diagnostics, Inc.

2016 Q4 Results Conference Call

Monday, February 27, 2017, 04:15 PM Eastern

CORPORATE PARTICIPANTS

Lawrence Mehren - *President and Chief Executive Officer*

Steve Reichling - *Chief Financial Officer*

Laura Pierson - *Investor Relation*

PRESENTATION

Operator
Good day and welcome to the Accelerate Diagnostics Incorporated 2016 Q4 Results Conference Call. All participants will be in 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 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, 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 Accelerate PhenoTest BC kit including accelerated identification and susceptibility results and estimates of time reduction to results.

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 gross 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 forward-looking statements are not guarantees of future performance and involve risk and uncertainties and that actual result 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 is 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 appreciate you joining us for our Q4 2016 conference call. I will begin with discussing our progress to date on key 2016 results. These include our recent FDA clearance and CE mark expansion, building of our commercial organization and ensuring operations excellence.

I will then turn it over to Steve Reichling who will review our preliminary fourth quarter and full year financial performance. I will conclude with a summary of our areas of focus for 2017 and then questions.

So let's start today with the welcome news that we have just received clearance from FDA for both the Accelerate Pheno system and the Pheno test blood culture kit. This is a significant milestone for Accelerate, and an important validation of our technology and the performance of our system.

The achievement of this milestone required over four years of dedicated effort from a large cross-functional team. When we began in 2012, we realized that to address the challenges of serious infectious diseases, we needed a truly disruptive instrument.

Our vision was to create the first direct from sample completely automated system that would identify a pathogen and perform antimicrobial susceptibility testing all in under eight hours.

Not only did it need to be fast, it needed to be highly multiplexed able to conduct any one of over 100 different assays. Initially there was a high degree of skepticism that such an instrument could be built.

To achieve this goal we needed innovation in many areas. For example, the system required a novel sample prep method that would clean a dirty sample, a genotypic ID system and a live cell phenotypic analysis engine.

Needless to say the engineering chemistry and biological challenges were significant but the Accelerate team along with a small group of truly forward-thinking external scientists and clinicians made it happen.

We built three generations of instrument each more capable and reliable than the last until we believed we had it right. We then ran tens of thousands of tests internally to optimize what became 140 different assays.

Our clinical study became what we believe is one of the largest trials and submissions ever in clinical microbiology. It included over 39,000 tests on approximately 1800 samples across 13 sites.

The final submission was over 10,000 pages long and included clinical study data for individual assays, multiple analytical studies and other important validations of our Pheno systems performance.

The final product has 140 assays of which 116 are FDA cleared with 24 available to be run in a research use only mode on the software. Of these assays some include labeling restrictions, a common practice.

In addition, we received clearance for what we have called our definitive monomicrobial test. This test when interpreted with the Gram stain had a 99.7% positive predictive value on fresh samples in the clinical trial confirming that additional testing is highly unlikely to identify additional bacteria or yeast and accordingly is not required.

This puts us in a unique position as we believe all other rapid systems require this additional testing. Using the data from the US trial we also expanded our claims in the EU filing a new CE Mark to include all of these tests. Accordingly we now have approval to market the Accelerate Pheno system and Accelerate Pheno blood culture test kit in our initial target markets of North America and Europe.

Now of course to capitalize on our R&D success, we need to achieve the same level of success with our commercial efforts. This journey has already begun. In the EU we worked hard in 2016 to build a team that matched the challenges of selling to 15 different countries each with different clinical and laboratory needs, healthcare systems, acquisition processes and reimbursement policies.

We believe the eight experienced professionals we hired have done a great job of addressing these challenges in capturing significant mindshare across the region. Further, they are translating this market awareness into real business.

We ended 2016 with numerous contracts and installed a number of modules. Further, two of these contracts were converted into installed accounts and began producing revenue in the final days of 2016. This progress has continued in 2017 and we expect solid performance for the remainder of this year and beyond.

2016 commercial progress in the US has also been positive. We completed the build out of our sales team with 25 seasoned professionals covering the entirety of the US and the major metropolitan areas of Canada. The early work of this team included market development and building a funnel of qualified leads. We believe both of these activities were successful with positive awareness in our target market translating into a healthy sales funnel on solid prospects.

We now have a number of signed pre-FDA approval contracts that were designed to allow customers to do a systematic evaluation against predetermined endpoints. If these endpoints are met, the contracts proceed to acquisitions. Now with FDA approval, we expect to begin seeing conversions of many of these contracts into revenue-producing acquisitions.

For example, within 30 minutes of FDA clearance we have received our first clinical capital order for four modules. This was an exciting start to our post FDA clearance sales effort. Supplying the commercial teams and their customers with a steady supply of high quality instruments and test kits is an important aspect of our continued success.

Accordingly in 2016 we expanded our manufacturing capability. We now have built over 390 instruments and over 100,000 kits which we believe will allow us to meet demand. Further we continue to in-source key component of our instruments and kits and are now close to what we believe is optimal vertical integration.

All in all, it was a great year for us. We conducted a major clinical trial, achieved FDA clearance and an important CE Mark expansion, built out two highly motivated and productive sales teams both of which are showing what we believe is solid early traction. We also optimized our manufacturing operations which are ready to meet what we believe will be strong demand and while we are excited about all of these positive developments, we are now laser-focused on 2017.

But before we get there, let me turn it over to Steve to review our preliminary fourth quarter and full year financial performance.

Steve Reichling
Thank you, Larry, and good afternoon everyone. Revenue for the fourth quarter was $39,000 and for the year ended December 31, 2016 totaled $246,000. Fourth quarter revenues contained $12,000 in sales of Pheno BC kit consumables across two European clinical reagent rental customers, one US PVP site, and one US research site.

No costs of goods sold were recognized in 2016 as inventory was charged to research and development expense. With FDA authorization obtained, we will begin capitalization of inventory and the recognition of costs of goods sold on product sales beginning Q1 2017.

Selling, general and administrative expenses for the quarter were $10.2 million and $36.2 million for the year as compared to $5.9 million and $17.9 million for the respective same period in the prior year. These increases were principally driven by personnel-related costs in our US and EU sales and marketing organizations.

Research and development costs for the fourth quarter was $5.2 million down from $6 million from the same quarter in the prior year. Research and development cost for the year were $28.2 million for the full year up from $26 million in the prior year. Both of these changes were driven by clinical trial and prelaunch inventory cost and timing.

Our net loss for the fourth quarter was $16.1 million resulting in a net loss per share of $0.31 on weighted average basic shares outstanding of $51.4 million. Our net loss for the year was $66.4 million resulting in a net loss per share of a $1.29 on weighted average basic shares outstanding of $51.3 million.

The net loss contained $2.2 million and $8.8 million in non-cash stock-based compensation expense for the quarter and year respectively. Net cash for operations in the quarter was $12.8 million and was $53.4 million for the year. The company ended the year with cash in investments of $77.8 million. We anticipate filing the 10K prior to market open on February 28th.

I will now hand the call back over to Larry for some closing comments.

Lawrence Mehren
Okay. So looking forward, in 2017 we will focus in three areas. First and most importantly we want to achieve a great launch of our Pheno system and Pheno test positive blood culture test kit. Success here will be determined by placements and ultimately revenue in line with consensus adjusted for the timing of our now achieved FDA clearance.

Our second initiative is maintaining product superiority and expanding the attractiveness of our current system and kit by adding additional assays, capabilities, features, and improvements. The first of these, an assay for Minocycline and Acinetobacter, we expect to submit to FDA in the next weeks.

Additional label expansions will likely follow along with new features such as resistance marker detection. Third, we plan to make progress on additional kits for the Pheno platform. In particular, we expect to achieve CE Mark for our respiratory kit in 2017 with an FDA clearance in 2018. This kit is significantly differentiated from other respiratory panels on the market in that it is directed at lower respiratory bacterial infections.

These infections are a leading cause of mortality and morbidity and commonly are resistant to standard antibiotic treatment. We believe our solution will be the first to provide direct from sample ID and antibiotic susceptibility testing, greatly decreasing time to result and improving clinical outcome. And with that I will open it up to questions.

QUESTION AND ANSWER

Operator
We will now begin the question and answer session. To ask a question, you may press "*" then "1" on your touchtone phone. If you are using a speaker phone, please pick up your handset before pressing the key, to withdraw your question, please press "*" then "2." At this time, we will pause momentarily to assemble our roster.

The first question comes from Brian Weinstein with William Blair. Please go ahead.

Matt Larew
Hi, good afternoon. This is Matt Larew for Brian. First question here on the PVPs, Larry you mentioned within 30 minutes that the first capital order came in and I'm just wondering what you think that the time line is going to look like here for additional conversions from your PVP relationships and how they will convert over commercial contracts?

Lawrence Mehren
Yes sure Matt, yeah that particular PVP was started and completed within three months. So we are hopeful that's the typical timeframe that we will see from others.

Matt Larew
Okay, fair enough. And then beyond those PVP customers just wondering if you have a sense of what the funnel looks like and for how many you know potential customers the sales force has engaged to date. And between the PVPs and initial customers, what kind of placement range you might be looking for here in 2017.

Lawrence Mehren
So Matt **,** I think you are asking for some view of what we think placements might look like in 2017 and as I mentioned earlier I think that consensus adjusted for FDA timing is about right and in terms of the timeframes and in terms of the funnel, look we have a robust funnel and we are excited about that and proud of that and the sales team has been working their tail off to make sure that we can achieve what we've suggested we'll achieve in 2017.

Matt Larew
Okay then the final one from me is here is on the respiratory product. The blood culture study I think you mentioned with 1800 samples and 13 sites, do you expect a similar size and like the time here for the respiratory trial?

Lawrence Mehren
So Matt we are hopeful that based on our experience with FDA and this first trial that the next trial will able to be a bit more contained and will be able to be a bit more efficient. We learned a lot in the first trial and we think we can apply that to the next trial. Further, FDA now has experience with us and with our systems so we think it should be a bit better. That being said, we have not had any formal discussions yet with FDA but now that we have been approved, we can begin having those discussions about our next kit.

Matt Larew
Okay, thanks, I'll let others get in.

Lawrence Mehren
You bet.

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

Tycho Peterson
Hey thanks, congrats on the approval guys. Larry, I think you've talked about the average hospital maybe requiring four modules. Can you give us a sense as to how you think about them taking on systems? Do you think that they'll do them on kind of singles and doubles until they get more comfortable with it and what are your thoughts also on utilization? How quickly will it take customers to ramp?

Lawrence Mehren
Yeah Tycho, look I do think that as mentioned that the average hospital to run our blood kit along with perhaps a bit of respiratory will take about four modules. We have enough I guess visibility into what that process looks like. I think initially many customers will take on between two and four modules, and then as volumes ramp up they will add an additional module. And as we add additional kits, I think they will add additional modules.

Tycho Peterson
And thoughts on pull-through on utilization, how quickly it takes customers to ramp?

Lawrence Mehren
Tycho, I think that once they begin to run this clinically, I think that we should see a relatively robust ramp.

Tycho Peterson
Okay. And then, can you maybe provide a little bit more color on the experience in Europe to date? Particular geographies you want to call out, and how we think about timelines for you to sign up distributors in general outside the US?

Lawrence Mehren
Okay. So in general, in Europe we are direct. So we're focused on 15 countries. And in all of those countries, we are direct. We will sign up distributors for Eastern Europe, Middle East, Africa, and we're in the process of doing that now.

In terms of specific color on certain countries, I can tell you that we've had great success in Southern Europe, particularly in Italy and Spain. And I think that has to do with both the quality of the sales representation that we have in those countries, as well as the need in those countries.

Both of those countries have real challenges with resistant infections and I think they've been looking for a device like ours for a long time. That being said, we are seeing good traction across all of Europe, and we think that the team we have there is quite good. As a matter of fact, I'd say that…and I think I mentioned this before that…the EU at this point is a bit ahead of our expectations.

Tycho Peterson
Okay. Thank you.

Lawrence Mehren
You are welcome

Operator
The next question comes from Karen Koski with BTIG. Please go ahead.

Karen Koski
Hi guys. Thanks for taking the questions, and congrats on the approval. First question for me, just in follow-up to Tycho's initial question, can you provide an update on how you are thinking about capital sales versus placements via reagent rental model, both in the US and in Europe?

Lawrence Mehren
Yes Karen. I can take this for you. I think the good news is that our module cost per unit is relatively low and that affords us a lot of options. I think we've talked in the past that we would expect a majority of the sales in the US to be capital and the inverse of that in Europe. Europe is more capital sensitive. We're likely to see more reagent rentals. And so far experience has played that out. We have two live now reagent rental customers in Europe, and our, as you heard our first sale out of the gate in the US was an all capital deal.

Karen Koski
Okay. And then can you provide any additional color around, Larry I know you mentioned that there are some end points that some of your….the sites that we're looking to validate the system pre-FDA approval we are working on. Can you provide any more color on what some of those end points might be and what data they've generated that is giving them confidence that this is a system that they want to adopt clinically?

Lawrence Mehren
Yes, sure Karen. The endpoints were primarily FDA approval, and the successful completion of their particular verification program. So as you know when a hospital lab takes on a new instrument, they have to go through a formal verification process, and that form of verification process is determined primarily by the individual lab and so typically, those were the two major end points that we've been talking about.

Karen Koski
Okay. That makes sense. And then just I guest lastly for me, when you think about all the various stakeholders that you need to get onboard whether it's the lab director versus the clinician, versus the **C suite** , who are you expecting to be kind of the most challenging to convince? And then based on your discussion so far, who have you been able to get the most traction with kind of right out of the gate?

Lawrence Mehren
Good question, Karen. Look I would say that it varies from site to site. We always need a champion and that champion can come sometimes from the lab, sometimes from the clinic and interestingly sometimes from the administration. I would say to make broad generalizations, the clinicians, we have the clinicians at HALO, they love our product, and anything that gets information that gets them to help their patients faster, they want. I would say, the administration is probably given the cost justification that we've put together, I think the administration is frankly probably the second easiest to convince and in general are very enthusiastic about our product and I'd say the lab directors are perhaps the most challenging.

Karen Koski
Okay. Thanks again for taking the questions and congrats again.

Lawrence Mehren
Yes. You bet, thanks Karen.

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

Bill Quirk
Great, thanks. Good afternoon and congrats on the approvals guys.

Lawrence Mehren
Thanks Bill.

Bill Quirk
First, question is, just Larry maybe help us think about the pace of clinical presentations and papers that are coming out of some of your research sites, just curious when we might see or hear data about things like any single site outcome studies or any cost-benefit analysis? Thanks.

Lawrence Mehren
Yes Bill, we have commissioned I think no fewer than 15 of these studies across both the US and Europe. The first ones will come out shortly at ACMED and then at ASM, I think we have also had a number of publications submitted to journals, but you should see all 15 of those come out over the course I believe of the next 12 months.

Bill Quirk
Okay, fantastic. And then a question for Steve, how should we think about OPEX trending here in 2017, I mean a lot of the clinical trial costs are I guess somewhat behind the Company clearly you'll have the respiratory trial to run, we're going to see the shift in the inventory built from R&D to cost of goods just help us a little bit to think about some of the pieces here. And then I guess the second part to that question is do you see the need to add any additional salespeople either in the US or in Europe that we should be thinking about as well. Thank you.

Steve Reichling
I think the more majority of our OPEX investment is pretty well in place and we did a lot of hiring during 2016. Of course you'll see the annualization effect of a lot of those sales hires in the year and as you mentioned that should…that annualization effect will be largely offset by not taking on the expense of a clinical trial this year. So, I think from a net cash burn perspective you're likely to see net cash burn similar to what we saw in 2016 for the whole of 2017.

With regard to your question for the number of salespeople, I think we're in a good place for 2016 but we'll of course look opportunistically to hot geographies in countries and feed the hot hands as it were.

Bill Quirk
Okay, got it. And then, just last question from me is just, maybe could you share a little bit of feedback from some of the initial installs? Is the system up time kind of tracking to what they expected, system performance all those sort of fun things.

Lawrence Mehren
Thank you, Bill, I will take that one. I'd say in general yes we have had some challenges at different sites, but I think in general people have been very pleased with the performance of the system and how it's been running.

Bill Quirk
Got it, thanks Larry.

Lawrence Mehren
You're welcome.

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

CONCLUSION

Lawrence Mehren
Okay, great. Well, thank you everyone for the time today and the questions. In summary, I believe our clearance by the FDA is a tremendous milestone and reflects a truly incredible effort put forth by our team and our clinical partners. I believe this milestone will motivate an already highly motivated sales team and our operations folks are ready to meet what we believe should be strong demand.

Finally, our scientists are ready to deliver exciting new products and features for this novel platform. It's looking great. Good evening and I'll speak to you soon. Thank you.

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

Exhibit 99.2

Accelerate Diagnostics Receives FDA Marketing Authorization for the Accelerate Pheno™ System and Accelerate PhenoTest™ BC Kit

TUCSON, Ariz., Feb. 23, 2017 (GLOBE NEWSWIRE) — Accelerate Diagnostics, Inc. (Accelerate) today announced that the U.S. Food and Drug Administration has granted the de novo request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for identification and antibiotic susceptibility testing of pathogens directly from positive blood culture samples. The blood culture kit is indicated for susceptibility testing of specific pathogenic bacteria commonly associated with bacteremia, the leading cause of sepsis.

The Centers for Disease Control and Prevention estimate at least 2 million people each year are infected with antibiotic resistant bacteria across the U.S. In addition, antibiotic resistance contributes to the morbidity and mortality of healthcare-associated infections (HAI) that kill an estimated 75,000 people annually. [1]

“The ability to provide not only rapid identification but also rapid phenotypic susceptibility ensures patients receive the most effective and appropriate therapy in a timely manner,” said James Lewis, PharmD, Infectious Diseases Clinical Pharmacy Coordinator and Adjunct Associate Professor at Oregon Health and Science University and member of the CLSI Subcommittee on Antimicrobial Susceptibility Testing. “We know each hour of inadequate antibiotic therapy increases mortality and that excessive use of broad spectrum agents drives resistance. The faster we can tailor therapy, the better things are for the patient and the potential prevention of antibiotic resistance.”

Culture based identification and susceptibility systems require time consuming manual procedures, resulting in laboratory processing time that often exceeds 48 hours. With the Accelerate PhenoTest™ BC kit, labs can reduce the turnaround time by testing directly from positive blood culture samples, producing results up to 40 hours faster than conventional methods.

The Accelerate PhenoTest™ BC kit is a multiplexed *in vitro* diagnostic test utilizing both qualitative nucleic acid fluorescence in situ hybridization (FISH) identification and quantitative antimicrobial susceptibility testing methods intended for use with the Accelerate Pheno™ system. The blood culture kit is capable of simultaneous detection and identification of multiple microbial targets followed by susceptibility testing of the appropriate detected bacterial organisms using morphokinetic cellular analysis (MCA) of individual microbial cells and colonies under the challenge of antibiotics.

The Accelerate clinical study included more than 39,000 tests conducted on 1,850 samples across 13 trial sites and exceeded the requirements of the FDA for identification and antimicrobial susceptibility testing. The study showed overall sensitivity of 97.4% and specificity of 99.3% for identification. For susceptibility, overall essential and categorical agreement versus standard broth microdilution was 96.3% and 96.4% respectively. [2]

The Accelerate PhenoTest™ BC kit includes 140 assays for both identification and susceptibility testing, of which 116 were submitted to the FDA. The kit also includes what Accelerate refers to as a "definitive" monomicrobial test indicating when a patient's positive blood culture sample has only one targeted pathogen. In the Accelerate clinical trial the monomicrobial result had a 99.6% positive predictive value (PPV) when evaluated in combination with the Gram stain. The monomicrobial result, matched with a Gram stain, allows microbiologists to report results without additional laboratory workup.

"We are excited to offer microbiologists and treating physicians earlier intelligence about the infections they fight on a daily basis," said Lawrence Mehren, President and CEO of Accelerate Diagnostics, Inc. "Bringing this solution to market has been a culmination of years of effort. I could not be more proud of the Accelerate team, more grateful to our clinical trial partners, or appreciative of the FDA's guidance throughout this endeavor."

The FDA granted the *de novo* request from Accelerate to legally market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for *in vitro* diagnostic use. The *de novo* classification process provides a regulatory pathway intended to expedite FDA review of novel low-to-moderate risk devices for which no predicate device exists when special and general controls demonstrate reasonable assurance of safety and effectiveness.

Accelerate will discuss the *de novo* request granted by the FDA with investors and analysts on its preliminary earnings conference call scheduled for, Monday, February 27, 2017 at 4:15pm ET. A live audio webcast of the call will be accessible from the investor portal of the company's website at axdx.com/investors.

Visit axdx.com to get more information about the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

References:

1. Reports from the Centers for Disease Control and Prevention can be found at cdc.gov/hai/surveillance/ and cdc.gov/drugresistance/
2. Overall results are based on FDA/CLSI 2016 breakpoints – see product labeling for additional detail

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. ("Accelerate Diagnostics,") (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 fully automated Accelerate Pheno™ system, and direct from positive blood culture Accelerate PhenoTest™ BC kit, leverage a suite of technologies to eliminate the lengthy culture and sample preparation steps required prior to testing. Using proprietary molecular identification methods and morphokinetic cellular analysis (MCA), the solution aims to reduce the time that clinicians must wait for quantitative antimicrobial susceptibility results necessary for optimal antibiotic selection, dosing, and infusion strategy, called minimum inhibitory concentrations, or MICs.

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

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, the 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 March 9, 2016, 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.

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