
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) **May 9, 2018**

Accelerate Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-31822

(Commission File Number)

84-1072256

(IRS Employer Identification No.)

3950 South Country Club, Suite 470, Tucson, Arizona

(Address of principal executive offices)

85714

(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 May 9, 2018, Accelerate Diagnostics, Inc. issued a press release announcing its financial results of operations for the quarter ending March 31, 2018 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:

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated May 9, 2018</u>
<u>99.2</u>	<u>Earnings Call Transcript, May 9, 2018</u>

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.

Date: May 14, 2018

ACCELERATE DIAGNOSTICS, INC.
(Registrant)

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated May 9, 2018
99.2	Earnings Call Transcript, May 9, 2018

Accelerate Diagnostics reports Q1 2018 financial results

TUCSON, Ariz., May 9, 2018 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. today announced financial results for the quarter ending March 31, 2018. The company generated revenue of \$801,000, up 51% from the prior year, and reported signed agreements for 345 instruments. Contracts for customer evaluations total 256 instruments while revenue generating placements grew to 89 across the U.S. and European regions.

“The team made considerable commercial and development progress to start the year, increasing awareness and adoption of the Accelerate Pheno™ system, and expanding its capability beyond bloodstream infections and sepsis to include patients with severe bacterial pneumonia,” said Lawrence Mehren, President and CEO. “By giving physicians the ability to optimize antibiotic therapy at least two days earlier, we continue to move closer to achieving our mission to dramatically improve outcomes for patients with these life-threatening infections.”

The company highlighted 12 recent customer studies shared at ECCMID, the European Congress of Clinical Microbiology and Infectious Diseases. These studies, all related to the Accelerate Pheno™ system, were shared at the congress by hospitals in Italy, Germany, Sweden, and the United States.

The company also reported progress on development of its severe bacterial pneumonia kit including alignment with the U.S. Food and Drug Administration (FDA) on a shorter and less complex, 510(k) regulatory pathway, for the test, along with the addition of two new pathogens and three additional antibiotics. The expected start of the U.S. clinical trial remains in late Q2 to Q3.

Mr. Mehren, together with Steve Reichling, the company’s Chief Financial Officer, will host a conference call to review the financial results, commercial progress, and development updates at 4:15 p.m. Eastern Time on May 9, 2018.

First quarter 2018 results

- Net sales of \$801,000 compared to \$530,000 in the first quarter of 2017
- Gross margin realized was 39%, impacted by one-time charges reported for the quarter
- Selling, general, and administrative expenses of \$14.4 million, compared to \$10.5 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 first quarter of \$6.8 million, compared to \$4.3 million in the same quarter of 2017 due to investments made in preparation for activities related to the U.S. clinical trial for respiratory
- Net loss of \$20.8 million, or \$0.37 per share on weighted average basic shares of 55.6 million shares outstanding, which includes \$5.6 million in non-cash stock-based compensation expense
- Net cash used in the quarter was \$16.2 million, ending the quarter with total cash, investments, and cash-equivalents from all activities of \$193.6 million

Full financial results for the quarter ending March 31, 2018 will be filed on Form 10-Q through the Securities and Exchange Commission’s (SEC) website at <http://www.sec.gov>.

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 August 9, 2018.

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 8101976.

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 10119275 until May 30, 2018.

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” and diamond shaped 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, 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 1, 2018, 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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Source: Accelerate Diagnostics, Inc.

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

	March 31, 2018	December 31, 2017
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 126,847	\$ 28,513
Investments	66,754	80,648
Trade accounts receivable	1,065	1,946
Inventory	10,127	8,063
Prepaid expenses	1,538	850
Other current assets	804	468
Total current assets	<u>207,135</u>	<u>120,488</u>
Property and equipment, net	5,851	4,890
Intellectual property, net	129	134
Total assets	<u>\$ 213,115</u>	<u>\$ 125,512</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,758	\$ 2,080
Accrued liabilities	4,578	3,636
Deferred revenue and income	117	1,071
Total current liabilities	<u>7,453</u>	<u>6,787</u>
Other long term liabilities	25	21
Convertible notes	99,162	—
Total liabilities	<u>\$ 106,640</u>	<u>\$ 6,808</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of March 31, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 75,000,000 common shares authorized with 53,950,083 shares issued and outstanding on March 31, 2018 and 75,000,000 authorized with 55,673,810 shares issued and outstanding on December 31, 2017	54	56
Contributed capital	414,262	360,620
Treasury Stock	(45,067)	—
Accumulated deficit	(262,833)	(241,972)
Accumulated other comprehensive loss	59	—
Total stockholders' equity	<u>106,475</u>	<u>118,704</u>
Total liabilities and stockholders' equity	<u>\$ 213,115</u>	<u>\$ 125,512</u>

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	March 31,
	2018	2017
Net sales	\$ 801	\$ 530
Cost of sales	492	26
Gross profit	309	504
Costs and expenses:		
Research and development	6,782	4,288
Sales, general and administrative	14,353	10,526
Total costs and expenses	21,135	14,814
Loss from operations	(20,826)	(14,310)
Other income (expense):		
Interest expense	(158)	—
Foreign currency exchange gain (loss)	55	(26)
Interest income	301	136
Total other income, net	198	110
Net loss before income taxes	(20,628)	(14,200)
Provision for income taxes	(184)	—
Net loss	<u>\$ (20,812)</u>	<u>\$ (14,200)</u>
Basic and diluted net loss per share	\$ (0.37)	\$ (0.27)
Weighted average shares outstanding	55,640	51,887
Other comprehensive loss:		
Net loss	\$ (20,812)	\$ (14,200)
Net unrealized (loss) gain on available-for-sale investments	(53)	11
Foreign currency translation adjustment	112	56
Comprehensive loss	<u>\$ (20,753)</u>	<u>\$ (14,133)</u>

See accompanying notes to consolidated financial statements.

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

	Three Months Ended	
	March 31,	March 31,
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (20,812)	\$ (14,200)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	539	505
Amortization of intangible assets	5	3
Amortization of investment discount	19	121
Equity-based compensation	5,602	3,215
Non-cash interest expense	158	—
Loss on disposal of property and equipment	11	—
(Increase) decrease in assets:		
Accounts receivable	881	(522)
Inventory	(1,917)	(4,155)
Prepaid expense and other	(653)	(457)
Other current assets	(336)	(280)
Increase (decrease) in liabilities:		
Accounts payable	701	276
Accrued liabilities	733	(4)
Deferred revenue and income	(1,003)	29
Deferred compensation	4	—
Net cash used in operating activities	(16,068)	(15,469)
Cash flows from investing activities:		
Purchases of equipment	(1,294)	(229)
Purchases of available-for-sale securities	(9,356)	(4,562)
Sales of available-for-sale securities	3,000	—
Maturity of available-for-sale securities	20,125	8,845
Net cash provided in investing activities	12,475	4,054
Cash flows from financing activities:		
Issuance of common stock net of issuance costs	134	189
Exercise of options and warrants	1,112	1,844
Proceeds from issuance of convertible note	150,000	—
Prepayment of forward stock repurchase transaction	(45,069)	—
Payment of debt issuance costs	(4,330)	—
Net cash provided by financing activities	101,847	2,033
Effect of exchange rate on cash:	80	55
Increase (decrease) in cash and cash equivalents	98,334	(9,327)
Cash and cash equivalents, beginning of period	28,513	19,244
Cash and cash equivalents, end of period	<u>\$ 126,847</u>	<u>\$ 9,917</u>

Accelerate Diagnostics, Inc.

First Quarter 2018 Earnings Conference Call

Wednesday, May 09, 2018, 4:15 PM Eastern

CORPORATE PARTICIPANTS

Lawrence Mehren - *President and Chief Executive Officer*

Steve Reichling - *Chief Financial Officer*

Laura Pierson - *Investor Relations*

PRESENTATION

Operator

Good day and welcome to the Accelerate Diagnostics First Quarter 2018 Earnings Conference Call. All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. To ask a question, you may press "*" then "1" on your telephone keypad, to withdraw your question, please press "*" then "2." Please note today's event is being recorded.

I would now like to turn the conference over to Laura Pierson. Please go ahead.

Laura Pierson

Before we begin, it is important to share 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 those that are not historical facts. These statements may contain expectations regarding revenues, earnings, operations and other results and may include statements of future performance, forward sales estimates, timing of clinical outcome data, timelines associated with the severe bacterial pneumonia test kits for use on the Accelerate Pheno™ System along with other plans and objectives.

Forward-looking statements include those 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 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 because 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 Diagnostics. Larry.

Lawrence Mehren

It is great to speak to you all. I have just finished doing a full review of our two focus areas for 2018, revenue and respiratory. What I thought was encouraging, but also highlighted some timing risks that I want to share with you.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

So let's begin with commercial progress in EU. Overall, we believe this geography is progressing quite well. We have just returned from ECCMID, the largest infectious disease congress in the EU. We showed quite well there with significant booth traffic, quite a bit of funnel progression and 100s of attendees at our symposia highlighting the benefits of rapid susceptibility in general and the Accelerate Pheno™ system in particular.

At this congress alone, 12 posters were presented highlighting the speed, accuracy and clinical benefits of our system and test. This now takes us to over 60 posters and publications worldwide that continue to demonstrate the utility of this system and more importantly are now showcasing the clinical value of the system. In particular, they demonstrate the system's unique ability to enable dramatic improvement to antibiotic prescribing, allowing for both rapid escalation and de-escalation of antibiotics.

And this is changing outcomes as evidenced by the data and presentations from La Princesa Hospital in Spain and Basingstoke and North Hampshire Hospital in the United Kingdom. In Basingstoke, for example, they have shown antibiotic treatment optimization, reduction in overall antibiotic use, narrowing of patients' antibiotics and implementation of infectious control procedures all a day and half faster on average than they were able to do before.

All of this is contributing to a bit of a tailwind in the EU, and while first quarter numbers were as we guided earlier very light, we did see meaningful progress. In Italy, for example, we now have seven customers up and running clinically with numerous customers deep in the funnel and expected to close over the coming quarters. We also are expecting a catalyst that we believe will continue to drive business in this country.

In the fourth quarter, we expect AMCLI [ph] the Italian Association for microbiology's clinical care working group to include our solution and guidelines for treatment of critically ill patients affected by bacterial infections. This is great for patients in Italy, and we hope we will be duplicated in other countries across the EU.

Other countries in the EU are also making progress, France, Germany, Spain and the UK among them. In each of these countries, we are implementing specific market access programs that are having a positive impact.

For example, in Germany, the biggest EU market we have two active customers and expect many more. One sticking point in driving faster adoption was the lack of a German specific health economic outcome model with live data from German hospitals. This is something we have now remedied. With this in hand, we expect progressive commercial traction from Germany going forward, as well as, the rest of our EU business.

Lastly, our business in the Middle East has been doing quite well and we expect good things from this region later this year. Overall good progress and as expected we should see a strong third and fourth quarter from this geography.

There is also progress in North America to start with our US pipeline remains quite strong. We continue to add scores of accounts to our funnel and many accounts are in the latter stages of acquisition and implementation. Our conversion of evals continues to be nearly perfect with very little attrition post-evaluation and instrument performance that we believe has been excellent. And while exciting changing the practice of medicine is not easy.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

I had the opportunity to have dinner this past Saturday with the mentor of mine, Dr. Tom Grogan, the founder of Ventana Medical Systems, my former employer. Ventana eventually was a hugely successful company, but Tom reminded me that the first few years of Ventana's launch like most diagnostic launches was quite challenging with first year sales of just three instruments.

And I do also see risk in our commercial launch. A year into it, we have tremendous interest and good progress. However, I believe our funnel remains congested. Sales are still taking too long and our efforts at speeding the process up have had mixed results.

For example, while we are increasing the speed of evals and connections to the LIS, the contracting process remains challenging. In numerous institutions across the country, we have the support of clinicians, the lab and the C suite, yet final sign off on our POs continues to extend.

I believe this is all about urgency. Many of you have done the same work we have done, surveying hospitals to see if they know of the Accelerate Pheno™ system and plan to buy it. And we believe the results of these surveys remain encouraging.

Usually a resounding yes, yet their urgency is different than ours. We don't want them to acquire tomorrow, we want them to acquire today. So we are redoubling our efforts to create the sense of urgency necessary to un-stick these accounts and most of these programs are already underway.

The first program is evidenced, something that we are actively driving. In addition to the 61 publications and posters on the Accelerate Pheno™ system, we expect an additional seven to be presented at the upcoming ASM.

Included in the publications, we now have clinical outcome results to further a test the value Accelerate Pheno™ system was providing. We are also initiating a registry for both our blood and respiratory kit that we expect will show the significant improvements to patient outcomes driven by Accelerate Pheno™ system results.

Most importantly, evidence is also coming that we expect will be a major driver later this year. In late 2017, two institutions, the Mayo Clinic, Rochester and UCLA, secured IRB approval to conduct a randomized clinical trial investigating the efficacy and associated health economic outcomes of Accelerate Pheno™ system. The trial randomizes patients with gram-negative infections into two cohorts. One group receives therapy based on standard-of-care, the other care informed by Accelerate Pheno™ system. Needless to say, this was a difficult study for which to secure approval, given the potential challenges of clinically impactful information and earlier optimized therapy.

Regardless, the study is nearing completion and we expect enrollment to finish in Q3 with early data soon after. If this study concludes as we hope it will demonstrate the improved outcomes for these critically ill patients with positive impacts on mortality, morbidity length of stay stewardship and cost. We can't wait.

The second program is securing contracts with group purchasing organizations, many of which are compliant. And I am happy to report that we are also making steady progress here. These contracts represent access to over 3,000 institutions and unlock a huge part of the market currently closed to us. This past week, final revisions were completed for the first of these contracts and we expect their counter signing in the next days. We expect the others to be concluded in the coming quarters. And while there is no guarantee of broad adoption in these institutions, this should be a significant catalyst for our sales efforts and speed up the contracting process.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

Thirdly, our KOL strategy is also working. We now have arguably the two most prestigious children's hospitals in the country as paying customers. We also have a number of the most prestigious cancer centers and tertiary hospitals using our device clinically. Also notable are the number of community hospitals that are finding the Accelerate Pheno™ system useful, even indispensable. We continue to be humbled by the stories of lives saved and overall improvements in hospital outcomes, including to the bottom line.

It is also helpful that a number of these customers have become real evangelists of the technology and not hired guns. These folks are just so darn excited by what they are doing and changing sepsis outcomes using the Accelerate Pheno™ system that they are encouraging others to consider our system. This is how it should work.

Finally, we have also reorganized the sales team to take advantage of the momentum created by these efforts. We have substantially increased our sales organization and recently completed extensive training of the new team we have brought to the effort. And while some ramp time for the new team as expected, we are already seeing benefits that will accrue in the coming quarters.

So all-in-all, we believe much to be encouraged about, solid data, great KOL support, good anecdotal evidence of clinical outcomes with definitive clinical data to come. For me, I now believe that we are no longer managing, if we will become standard-of-care in much of the world, but when. That is a good feeling and has the team very pumped up.

So as we guided previously, we had the very light Q1 we expected and still expect to have a light Q2. We do expect to see a heavy Q3 and even heavier Q4. The funnel right now looks to get us to the bottom end of our guidance range albeit with some risk and how we end Q2 will obviously have a material impact.

And with that, I will turn it over to Steve to review our financial performance. Steve.

Steve Reichling

Thank you, Larry and good afternoon everyone. Revenue for the first quarter was \$801,000 compared with \$530,000 from the same quarter in the prior. This increase was a result of sales of the Accelerate Pheno™ System and Accelerate PhenoTest™ BC kit across the US, Europe and Middle East.

Cost of goods sold for the first quarter were \$492,000 resulting in a gross margin of 39%. This gross margin includes one-time charges and the effects of excess capacity which negatively impacted our quarterly margin. We believe these items will not have an impact on our outlook for a strong full-year gross margin.

Selling, general and administrative expenses for Q1 was \$14.4 million compared with \$10.5 million for the same period from 2017. This year-over-year increase was driven by higher selling personnel related costs in the US.

Research and development costs for the quarter were \$6.8 million and \$4.3 million for the same period in the prior year. This year-over-year increase was due to investments made for the preparation of our US respiratory clinical trial and expanded clinical affairs activities.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

Our net loss for the first quarter was \$20.8 million resulting in a net loss per share of \$0.37 on weighted average basic shares outstanding of 55.6 million. This net loss contains \$5.6 million in non-cash based stock compensation expense.

Net cash used for the quarter was \$16.2 million, the company ended the quarter with cash and investments of \$193.6 million which includes net proceeds of approximately \$100 million from the convertible offering, but excludes the additional approximately \$21 million of net proceeds from the Greenshoe exercised in April. Additionally, today, we have signed agreements for 345 instruments, of these 256 are under evaluation contracts and 89 are placements. We anticipate filing the 10-Q for this quarter later this evening.

And I will now hand it back to Larry to review our progress on research and development.

Lawrence Mehren

Thank you, Steve. In Q1, we made considerable progress on our second focus area for 2018, the completion and trial of our severe bacterial pneumonia test kit for use on the Accelerate Pheno™ system.

First, as we have previously mentioned, we remain in active discussions with FDA and these continue to go well. The dialogue continues to center around trial design and necessary analytical studies. We have however received surprising and encouraging news from the agency on the regulatory classification. They notified us recently that the products will be a 510(k), a de-classification from the sepsis kit which was reviewed as a de novo device.

The net result of this is a shorter path to approval and a less complex review process. And while we are hopeful that these discussions will conclude soon, we are taking this opportunity to introduce a recently developed automated sample preparation instrument into the trial.

We believe this device [indiscernible] upon current microbiology sample preparation workflows, enabling the use of Accelerate Pheno™ system on numerous sample types and applications including respiratory. One of the immediate benefits of applying this is improved reportability from complex samples, particularly those with interfering substances such as anti-microbials.

Lastly, we believe the output of this device is suitable for diverse microbiology application, enabling it to feed other workflows we are currently developing. Needless to say we are excited about this device and believe securing its approval as part of our respiratory trial, while adding some schedule risk is well worth it.

In Q1, we also completed adding three additional drugs and to two IV targets to the pneumonia panel to make the product even more appealing allowing it to assist and guiding treatment for some severe community acquired pneumonia, potentially increasing the products overall TAM.

Given this progress, we continue to expect to initiate the US regulatory trial in Q2 or Q3. Further, given our 510 classification, we expect a launch relatively soon thereafter. We will let you know more as soon as we conclude with the FDA.

Lastly, we are nearing initiation of a multi-center clinical outcome study in support of our severe pneumonia product. The study is targeted to begin in Q2 and includes a number of leading academic hospitals. The first phase of the study will establish a baseline for the time to current culture based antibiotic susceptibility results in serious pneumonia, along with outcomes and management practices.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

The second phase will be a perspective, randomized clinical trial that will evaluate both analytical and clinical performance. This outcome study is powered to demonstrate impact on length of stay, mortality and serious complications associated with hospital on-set and ventilator acquired pneumonia. We expect to have data available from this study right around the time we launch and believe this evidence will significantly shorten time to adoption.

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

QUESTION AND ANSWER

Operator

Thank you. 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 the speakerphone we ask you please pick up your handset before pressing the keys. To withdraw your questions, please press "*" then "2."

Today's first question comes from Tycho Peterson of JP Morgan. Please go ahead.

Tycho Peterson

Thanks. I guess, Larry you know, given the magnitude of the miss relative to The Street, I think there is a lot of focus here on, what is going to take to un-stick these accounts. You talked about a little bit of it, but you had that poster and publications out there for a little while, your placement did get cut half sequentially. I guess, can you help us give...get some comfort there, you know, these initiatives are actually going to pay off here? Can you also address the fact that you didn't preannounce given the magnitude of the miss? And then, it sounds like you've about you know, 25 million worth of systems that have been in the field for about a year a 100 or so, why haven't these converted at this point?

Lawrence Mehren

Okay. So Tycho, I appreciate the questions, you will have to help me, if I forget one of them there is a lot of them there. So I think in the first case as it relates to The Street's guidance, we didn't provide guidance on a quarterly basis and accordingly we didn't feel it was necessary to preannounce. At the end of the day, we did guide that our first quarter would be quite light, our second quarter would also be quite light, the third quarter would be heavy, and the fourth quarter would be heavier. So I think we are on track to achieve just that. And further, we've reiterated our guidance for the year on this call.

Secondly, I would say that in the first quarter we had a number of new pieces of evidence presented including that which was recently presented at ECCMID. I think that will help, and I think the rest of what we are doing as articulated in the conference call will also be quite helpful. You had another question which I missed that third question.

Tycho Peterson

You have had a decent number of systems sitting in the field for over a year, you know; I think it's around \$25 million worth. Why haven't these converted, some of the earlier evals, why are they still under evals and haven't converted at this point?

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

Lawrence Mehren

I think the good news Tycho is they are all in play. So we haven't lost a single one, I think it's taking quite a long time to contract. I mean, we do not have the benefit of being a reimbursed device. So unlike other folks out there that can rely on reimbursement, we actually have to rely on demonstrating health economic outcomes and sometimes that's challenging. I think we have done a really good job of that and are in the process of converting most of those instruments, and we expect frankly a majority of those to convert this year and that's what's really driving our optimism that we will have the year that we projected.

Tycho Peterson

Alright. And just one last one, I guess, if we think about the efforts to unstuck the accounts, you know, is there anyone in particular that stands out as potentially being more meaningful? I mean, if I think about the sales reps you are hiring, are you hiring at a more senior level or are there other factors here that of those initiatives you've listed that could be more impactful?

Lawrence Mehren

Yes, I would say two things. First of all, the ARLG study which includes Mayo Clinic, Rochester and UCLA. If that comes out as we expect it will, demonstrating what all of our customers have so far experienced which is a significant improvement in patient outcomes. And that's done in a prospective way, it's very difficult for a hospital than to not adopt, I think we will have created a situation where I don't want to be hyperbolic, but it's almost malpractice not to have this. And I think that could be a significant catalyst.

Secondly, it's important to note that we increased our sales force by almost 50%, and a number of those folks, I would say, over half our sales force has less than three months in the seat. So those folks are coming up to speed right now. Frankly, they have just been trained and we are already seeing great things. So I remain quite optimistic.

Tycho Peterson

Alright. Thank you.

Operator

And our next question today comes from Bill Quirk of Piper Jaffray. Please go ahead.

Bill Quirk

Great, thanks. Good afternoon, everybody. So, Larry just going back to you comments about the lower respiratory product, and specifically thinking about the front-end piece to that, you mentioned that or kind of implied I think in your comments that could create some additional time...turnaround time rather with respect to the clinical trial. Is the device itself, is it finished at this point any remaining technical risk or anything like that associated with it or are we ready to go here from a clinical trial standpoint? Thanks.

Lawrence Mehren

Yes, Bill. Thanks for asking. Yes, I would say there is still technical risk, and we will be optimizing and integrating write-up until the day that we enter clinical trials. We are always searching for perfect performance and as we are continuing to optimize, I would say, if we run into a challenge it's not going to present binary risk because the test works great, but it creates a timeline one. So with all that being said based on what we are seeing, we still expect to start our clinical trial in Q2 and Q3.

Bill Quirk

Okay, and given the preliminary data that's affiliated with that which obviously was quite strong. So Larry, is this a question of, you know, you have some optimality here where you can take this into the clinic without the sample prep device if...to your point, you are optimizing up until the last second. And if you don't get there, can you still move forward on this and incorporate this later, I mean, how should we think about that being a potential bottleneck to getting the clinical trial started?

Lawrence Mehren

Yes, it is a good question, Bill. I think, yes, we do have optionality. At the end of the day what we are trying to do is have just a home run here on both the technical perspective, overall performance outcomes and we really want to drive as perfect a product as we possibly can. And we are going to be, as I said optimizing until the very last moment, but we already have something that works really, really well and is better than anything else out there.

Bill Quirk

Okay, got it. And then just two more quick ones from me, on the Italian guidelines, can you talk about whether or not you are getting close with any other country, I assume, perhaps you are up just giving the Accelerate Pheno™ system has been there a little longer? And then secondly, given the economic study that came out of University Hospital or the mortality study that came out of University Hospital. Is that something that you guys are using with respect to trying to get these systems closed faster, I am just thinking about a scenario where you could you end up going to the hospital C suite, and trying to do it kind of a top down push just trying to get these things up and running, curious on your thoughts there? Thanks.

Lawrence Mehren

Yes. So as it relates to University Hospital, yes, we are excited about the white paper that came out, it's been helpful to us and for sure it's a...it's assisting our salespeople moving stuff forward. I would say though that because it's a pre-post observational study, it's not nearly as powerful as a study that is fully randomized like the Mayo Clinic study. So I think the Mayo Clinic study will be much more powerful and creates a much more of a tailwind than does the Augusta work, but the Augusta work, as well as, our other customers who have put forward a number of papers and publications about clinical data. Those are all helpful to us. So we are excited about that, but I really do think prospective randomized trial is the gold standard and more powerful.

As it relates to Europe, I think the answer is, no. I don't think we are close to guidelines in any other country. But we are making a significant progress in Germany, as well as, in France with reimbursement. So those would be significant catalysts for us and we expect by the third quarter to hear about whether we achieve the first step of reimbursement in both of those countries. So I think good news overall.

Bill Quirk

Thank you.

Lawrence Mehren

You're welcome, Bill.

Operator

And our next question today comes from Brian Weinstein of William Blair. Please go ahead.

Brian Weinstein

Hi, guys. Thanks for taking the question. Larry and Steve, looks like the funnel isn't it really growing that much right now 259 now 253. Can you talk about what's causing the front end to that funnel to maybe not have any kind of acceleration there? Is that anything due to the competitive environment you are seeing today relative to competition versus like molecular ID and resistance products or [indiscernible]? And do you think that your product actually can live side-by-side with those other products in the lab or do you think it really has to be a one or the other?

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

Lawrence Mehren

Okay, so...Thanks Brian. Look, as we mentioned we have a substantial funnel. I think, it's grown significantly, I think we now have more than 750 perspective customers in North America alone. Again, this is a congestion problem not a demand problem. And we actually didn't lose evals in Q1 we added ten new customers and converted several more. So...and in addition we had a number of...or a couple of customers purchased directly. It's important to note that total evaluation instruments that number is a rolling number and will decrease as customers convert. And frankly in Q1, finally, our sales team was really being reorganized and, you know, that was the first priority. I would say, we should see significant progression in Q2, Q3 and Q4. So I do not see this as a stoppage or anything, I think this was...we took a pause to put in place the things that we needed to put in place. And my expectation is that Q2, Q3 and Q4 should be quite good. I would also say that competitive situation is not what's holding us back at all. We are not in a situation where we are going to head-to-head against a molecular device and finding ourselves wanting. And I think in many cases we co-exist. So we have many co-exists with a molecular placement and you would see them running a respiratory viral panel while we are running those blood samples. So I would expect that to continue in a number of accounts and frankly in some accounts we are going head-to-head against molecular devices and typically we are winning.

Brian Weinstein

Alright, last quarter you mentioned the China feasibility study that you had commissioned. Obviously, it's a huge market and you said you might have an update for us on that in a couple of months. Where is that now and what were the results of that study, if you can share that?

Lawrence Mehren

Yes, sure. China looks very good for us. Reimbursement looks quite good for us and the market looks appealing. We are heading over...our team is heading over to China in two weeks to deepen the investigation, meet with KOLs and commission, a number of studies. So we are enthusiastic about progression there.

Brian Weinstein

And then at the end of the prepared remarks on the Q4 call, you did mention the pharma partnerships at that point. Are you able to expand on what that comment was referring to and the timing to hear more about this?

Lawrence Mehren

Yes, look...I think in this case, we are working with a number of pharma groups and a number of different deals and that's all I would like to say about it right now.

Brian Weinstein

Okay, thank you.

Operator

And our next question today comes from Sean Lavin of BTIG. Please go ahead.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

Sean Lavin

Thank you very much on for taking the questions. I guess, my first one just kind of given the numbers of systems you have...as Tycho brought up or is there a couple of points or are you at the point where you start taking some back to kind of encourage hospitals to start buying them?

Lawrence Mehren

No, Sean, I mean we wouldn't take them back unless the hospital is said that they are not interested or not going to buy them. And so far we have not had that happen. So we are not finding the situation where we've got hospitals that are saying we don't want to buy and quite the opposite, we are saying most of our situations are that we have hospitals that are working very, very hard to purchase those instruments and it's an internal struggle for them.

Sean Lavin

But if a hospital can keep using a system and doesn't have any threat of losing a system, and what makes them wake up on a certain day and say here's payment what incentivize that?

Lawrence Mehren

Well, I mean, first of all, it doesn't make sense for us to be installed when that hospital is in the process of moving things through their various committees. I would give you an example, like we have a number of hospitals where they have five, six or seven committees, each one meeting in a month or two times. So while that hospital is moving through that process of acquisition and securing budget and most of the time given where we are, that's not something that have been budgeted for in 2017. So it's off-cycle budget which takes a longer time. So Sean, we don't think it make sense to de-install them when they already are highly motivated to get this approved.

Sean Lavin

Okay, and as you think about your guidance and certainly the confidence in the back half, is there anything you can kind of point to that gives you that confidence or are there certain hospitals they said we could rather pay in the third and fourth quarter or you've gone through a number of hospitals, you've looked where they kind of where they are in the different committees. I mean, is there something you can kind of point to say, this should really pick up later this year instead of it being hoped but more kind of materials things you can point at?

Lawrence Mehren

Yes, sure we have many customers that are in the bottom end of funnel that are past evaluation those evaluations have been exceptional they've said they are going to purchase and they are going through committee right now and we have enough of those that even with attrition we believe that we will be in good shape.

Sean Lavin

Okay, thank you very much.

Lawrence Mehren

You bet.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern

CONCLUSION**Operator**

And thank you, ladies and gentlemen. This concludes today's question and answer session. I would like to turn the conference back over to Larry Mehren for any closing remarks.

Lawrence Mehren

Alright, thanks for the questions and I would say as usual a special thanks to our great team. They are doing a fantastic job. Another, great thanks to our dedicated customers and our really committed shareholders. You are all making it happen and as I said earlier, I think it's just now about when, and I think we are on our way...we are absolutely on our way. Cheers and I will speak to you soon.

Operator

Thank you, sir. Today's conference has now concluded and we thank you all for attending today's presentation. You may now disconnect your lines and have a wonderful day.

Accelerate Diagnostics, Inc.
Wednesday, May 09, 2018, 4:15 PM Eastern
