

Accelerate Diagnostics (AXDX) Is About To Accelerate Downward- \$6 Price Target

- White Diamond's proprietary diligence identified new info that suggests Accelerate Diagnostic's (AXDX) Pheno system is only a niche product.
- The Pheno system is not capable of replacing tissue culture methods due to design flaws and a questionable value proposition.
- Management has missed its reagent revenues per system target by over 30% and no one is talking about it.
- Pheno system lease agreements do not penalize hospitals for low test volumes, which hurts annuity revenues and AXDX eats the cost for upfront installation and validation.
- Highly anticipated results of the upcoming Mayo/UCLA study will likely be a bust, revealing no statistically significant improvement in LOS (Length of Stay) or patient mortality.

White Diamond's New Findings will prove why AXDX's Pheno system is unlikely to realize the revenue the street is expecting. The issues we have found have been missed by most.

Accelerate Diagnostics (AXDX) is a rapid diagnostic company that relies on one product, the Pheno system, utilizing PhenoTest diagnostic panels. The stock has been up over 70% in the year which we believe has created a very juicy shorting opportunity. What amazes us is that despite the continuous rise in stock price, the company has continued to miss earnings and other important metrics over the past year. We then dug deeper to figure out the fundamentals of the company and quickly realized that AXDX is selling a flawed product that is disputed by many stakeholders/professionals in the industry, and that their recent change in business model from a capital sale to a rental model will not save them from their fundamental issues: slow traction, sales and adoption rates. This information has not been realized by the market yet.



For a brief background, AXDX claims that it founded the Holy Grail of rapid sepsis diagnostics, because it delivers both bacteria type identification (ID) and anti-microbial susceptibility (AST) data faster than conventional cell culture testing. AXDX has received FDA approval for its system and diagnostic panel more than two years ago. The market is optimistic about AXDX's future and prices it at about a billion dollar market cap.

In contrast to enthusiastic AXDX bulls, hospitals largely ignore the Pheno system. AXDX's 2018 annual revenue was only \$5.6M. Both Q1 and Q2 2019 revenues were a meager \$1.8M. In Q4 of 2018, faced with the difficulty of selling Pheno systems to hospitals, AXDX changed its business model and adopted the lease model (aka the reagent revenue model), to reduce hospital commitment. The number of leased systems spiked initially, but then rapidly fell below management's expectation in Q2 2019.

Accelerate's History And Tight Insider Control

AXDX was formerly known as Accelr8 Technology Corporation. Accelr8 was run by a team of software engineers with some [shady histories](#). [In January 2001](#), Accelr8 purchased the OpTest technology assets from DDx, Inc. for \$0.5M in cash and \$2.5M in stock. This purchased software with some modifications is still a core of the AXDX technology today.

The two technologies utilized in the Pheno system are MCA (Morphokinetic Cellular Analysis) and FISH (Fluorescence in situ hybridization). FISH analysis is providing rapid identification (ID) of the microorganism, while MCA is used as a surrogate for Anti-Microbial Susceptibility (AST). A detailed explanation of the PhenoTest is given in [this peer-reviewed publication](#). Of importance is that the Pheno system relies on traditional cell culture, because a positive blood sample is required prior to performing the PhenoTest.

Today, AXDX shares are largely controlled by the Directors and largest shareholders, such as Jack Schuler, Larry Feinberg from Oracle investments, and Larry Mehren, AXDX's current CEO. In [April 2012](#), through Abeja Ventures, Mehren, Schuler, and John Patience, AXDX's Chairman, bought 14M shares for \$1.03, with warrants for another 7M shares at



\$1.03 and 7M at \$2.00. These warrants were exercised in 2013, giving them stock which is now worth over \$500M which they only paid \$35M for.

In sharp contrast to Accelerate’s claims, the Pheno is a niche product not designed to replace tissue culture methods

Mehren ended AXDX’s Q219 [earnings call](#) with:

“Thanks to our Board, who knows that we will be the standard of care and to our patient shareholders, thank you. We are on our way.”

In this report we present a compelling argument both from our research and from published literature that Pheno system will not become the standard of care and will not replace the standard cell culture methods, despite Mehren’s claim.

For a starter, we looked at the conclusions of a peer-reviewed [article](#) titled: Evaluation of the Accelerate Pheno system: Results from Two Academic Medical Centers. This article provides a very detailed assessment of the limitations of the PhenoTest, including the statement that Accelerate’s Pheno system will not be able to replace the standard of care. It states:

Another limitation of the system in our study was the high number of instances in which routine identification and AST were (not) recommended by the Accelerate Pheno system (26.8% of the time). This was because of technical failures (n = 21), indeterminate results (n = 36), or off-panel organisms that were not identified by the Accelerate Pheno system (n = 23). This implies that the Accelerate Pheno system, as tested in this study, will not be able to replace the standard of care. It will rather serve as an adjunct to the standard of care.

What authors are saying here is that the Pheno system failed in almost every third test due to three reasons: (i) Pheno system technical issues; (ii) results that were inconclusive (due



to a low number of bacteria in the positive sample); (iii) bacteria that is not covered by the Pheno system. The hospital, therefore, paid for the failed Pheno system tests and had to run the standard cell culture in parallel, just to get the correct antibiotic treatment without delay every time the Pheno system fails.

Major Diagnostic Companies do not care about AXDX, considering it a niche player with an unproven value proposition. We attended the 2019 ECCMID conference to better understand how big diagnostic companies view the Pheno system. Are they scared that hospitals would stop purchasing their equipment in favor of the faster Pheno system?

All the reps we talked to thought that the PhenoTest does not threaten their business of selling traditional cell culture tests, because the Pheno does not have capabilities of the standard cell culture based tests, such as, much broader coverage of microorganisms and antibiotics or the ability to process, for example, the urine samples.

Here is a response from a BioMerieux rep:

Accelerate is complementary to Vitek, because it works with blood stream infection only and our system is much broader. Blood stream infection is a very limited market. We work on everything, urine samples, for example. They only work on blood samples, which is 5% of the tests.

Here is an excerpt from a discussion with a ThermoFisher rep:

You can do PhenoTest, but then you should still get it reconfirmed by the cell culture test to be sure. Using cell culture plates you can know the exact effect of antibiotics on the microorganism, but if you are using the surrogate measurement (e.i. PhenoTest), then it is often just an indication, not the final answer.

Here is a response from a Beckman Coulter rep:

They are not really our competitors, because they still need to confirm AST results with standard methods. For example, Accelerate tests only 9 microorganisms, while we test



for all ranges of thousands of microorganisms. Even if they test the organisms that are within their panel, the test needs to be confirmed by the cell culture test. It is an additional test to give clinicians some guidance. For example, if Pheno does not detect an organism, the money is just wasted.

The biggest drawback of the Pheno system is a narrow coverage of microorganisms and antibiotics

When the FDA approved the PhenoTest 510K application in [February of 2017](#), it also identified [limitations](#) of the test system. According to [this peer-reviewed article](#), the FDA approved the PhenoTest for a limited number of organisms and antibiotics. The articles states:

The Accelerate PhenoTest BC kit can identify 16 organisms—6 Gram-positive and 8 Gram-negative bacteria, as well as 2 Candida species—directly from positive blood cultures. It is FDA cleared to provide AST data for 6 Gram-positive drugs, 2 Gram-positive resistance phenotype markers, and 12 Gram-negative drugs.

The same [article](#) further stated:

There were 298 blood cultures included in the study, and the Accelerate Pheno system provided a definitive identification result in 218 instances (73.2%). The Accelerate Pheno system provided a definitive and correct result for 173 runs (58.1%).

This result is truly staggering! The PhenoTest provided proper results in a mere 58% of cases, a bit better than a flip of a coin.

Narrowness of Pheno coverage is a repeated theme in scientific literature. In this [poster abstract #2826](#), presented at the 2019 ECCMID, authors concluded that the PhenoTest's



“major limitation is that it does not cover all the pathogens that may be responsible for sepsis”

At ECCMID 2019 we interviewed an AXDX rep to better understand the reasons for a narrow coverage of their test. It appears that it is linked to a fundamental limitation of the FISH method, used in Pheno system for ID testing.

Q. In your German study reported here, in 15% of cases the PhenoTest panel was either not broad enough or the number of cells were insufficient. How are you planning to address this limitation of your test system?

A. 15% is about accurate. Our panel covers about 85% of organisms. Our panel does not cover 100% of bug/antibiotic combinations, so you still need cell culture. It is not easy to cover 100%, because we use FISH probes and they may not be available for some bugs. Because of the FISH method we are somewhat limited.

The AXDX rep confirms above that the Pheno system doesn't replace cell culture, thus it is an adjunct to standard of care, not a replacement.

The PhenoTest analyzes only one sample at a time. If two samples need to be tested, the second testing module needs to be acquired, which is an additional expense and lab space

One Pheno system module is capable of processing only one sample at a time. This is a significant limitation, because of two reasons:

1. If two people gave their blood samples with an interval of less than 7h, the sample from the second patient must wait until the first sample is analyzed. This effectively negates the advantage of a shorter test time using Pheno system.
2. Another issue is having multiple samples from the same patient. It is a common practice to collect several blood samples from the same patient*, because of



contamination risks. The question therefore arises which sample to test with the Pheno system, if, for example, two or more samples from the same patient turns positive?

* from [Blood Culture guide](#) : *In order to distinguish between contamination and true bacteremia, a total of three to five blood culture sets should be sufficient.*

To address the one at a time sample flow limitation, AXDX advertises the modular design of its Pheno system. A customer may acquire additional testing modules if one is not enough. But it is not clear if a modular design truly saves space and money to its customers. ADXD [specifies](#) that a one module system takes 3 ft of bench space, while a four module system takes 7 ft of bench space, which is a lot! As one can see from the picture below, modules are bulky. The only part, which is shared, is a Touch Screen and a Computer, both of which are commodity items. This makes us think that adding a module is almost as expensive as adding another Pheno system, because the savings on the shared Computer and Screen are insignificant.



[Source](#): Accelerate Diagnostics Website

When we attended the ECCMID 2019, we noted that many startups are leapfrogging AXDX by designing their system to be capable of analyzing multiple samples.

Here is an excerpt from our conversation with a QuantaMatrix rep:

Q. How is your product different from the Pheno system?

A. Similar technology, also phenotype. Major differentiation is capacity, drastic difference is that we have positions for 12 blood samples, continuous loading. We have



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gram-positive and gram-negative sections. We have 15 position panels for antibiotic screening. Accelerate has just one sample analyzed at a time.

From our conversation with an Avails Medical rep:

New systems that are coming out will be lower cost, and they will also test more than one sample at a time. Accelerate has a module that can do one sample at a time and you need 7 hours to process the sample, so all other samples will wait till this is done. What do you do? You need to buy the second system to truly incorporate it into rapid AST testing. It is modular with Accelerate, but then you pay a multiple.

From an interview with a Gradientech rep:

We have some advantages over Accelerate – faster, cheaper and very precise. We have a small system you can run up to 12 samples from one screen controller. It is important to have a smaller, cheaper system that can run multiple samples for a hospital or a lab to adopt the product.

We would like to summarize our observations with the supporting quote about limitation of Pheno system from the peer-reviewed [article](#)

Other considerations for clinical microbiology laboratories are cost (of both the instrument and individual kits), laboratory space, workflow in the laboratory (only one sample per unit at a given time, although the system can accommodate up to 4 modules), storage space for the large single-use kits, and waste disposal of the kits.

Pheno system is wasting hospital money on ID testing, which can be done cheap and fast by MALDI

PhenoTest is very expensive, because it measures both ID (identification of micro-organism type) and AST (Antibiotic Susceptibility Test). Today, another rapid ID



diagnostic test, called MALDI, is [broadly advancing](#) into labs in the US and internationally. At ECCMID 2019, the companies developing next generation of rapid AST testing, told us that MALDI is the new standard for the rapid ID and it does it much cheaper, than Pheno system. As shown in this [article](#), the use of MALDI realized a net savings in reagent costs of 88% compared to traditional methods. At the price of \$200 per reagent kit, Pheno is substantially adding to the reagent cost, not saving! We are not sure how much more expense ID testing adds to PhenoTest, but the other companies, developing new rapid AST test, are concerned about cost reduction and are not including ID in their design.

From an ECCMID 2019 discussion with a Qlinea rep:

Q. How are you different from Pheno system?

A. We have a similar approach. We have taken away ID, because many labs in Europe have already invested in MALDI and that solution is good. So we can reduce the price of our product.

The criticality of AST testing for blood infection is over-hyped: physicians seldom use ID and AST data to adjust their treatment of sepsis

We spoke to a former practicing physician, who focused on critical care and was working in an Emergency Care Unit. Here is his view on the problem:

Q: Why are Accelerate Diagnostics, T2 Biosystems and other rapid diagnostic companies struggling to get their system adopted at the hospitals?

A: If you go to a physician and tell him: would you like it if I give you information on what pathogen is present in the blood stream much faster? The Physician would answer - sure, I'd like that. But if you ask him a different question: how often would this



information help you to change the patient infection management whether you know or do not know what pathogen it is? Then the answer is it's a very small percentage, because in most cases, if patients are sick enough, they will be placed on board spectrum antibiotics. So data rarely changes the management.

We looked at the clinical guidance for sepsis management and found no mention of the importance of rapid ID or AST testing. From analyzing the influential [Surviving Sepsis Campaign](#), the most critical aspect of sepsis management is to treat it as a medical emergency and perform a bundle of specific actions within the first hour of sepsis signs, which are:

- Measure lactate level.
- Obtain blood cultures prior to administration of antibiotics
- Administer broad-spectrum antibiotics
- Rapidly administer 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L
- Apply vasopressors if patient is hypotensive during or after fluid resuscitation to maintain mean arterial pressure

The IDSA (Infection Diseases Society of America) [Guide](#) for utilization of the Microbiology Lab does not provide any recommendation on using rapid diagnostics. Instead, in its chapter on bloodstream infection it mainly discusses blood sample collection and transportation to minimize contamination and how to improve success with the cell culture test.

[Here](#) is a very interesting observation about the value of AST testing, expressed by a renown expert, Dr. Christopher D. Doern from Virginia Commonwealth University Health System. He expressed his opinion, when writing an editorial note on the Pheno system investigation paper.



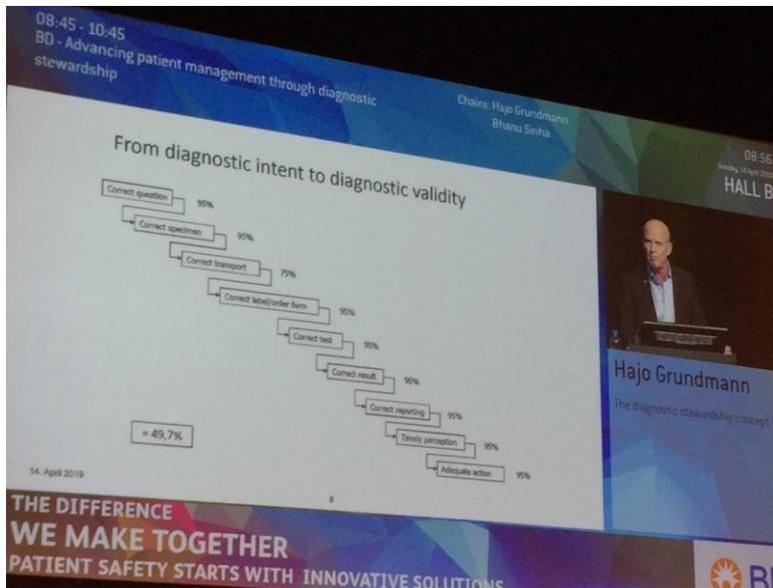
Despite the supposedly critical nature of these results, the practice of performing manual, direct AST, is far from commonplace. Why is this? Perhaps it is simply a matter of a cumbersome workflow, and laboratories do not have the staffing to perform the testing. Or perhaps, it is the fact that phenotypic AST for blood cultures does not matter as much as one might like to believe.

What is Dr. Doern's rational for questioning the value of phenotypic AST data? We looked into the peer-reviewed article, Dr. Doern quoted, and found the study [here](#), which concluded:

With respect to antimicrobial management, the most important information provided by the clinical microbiology laboratory appeared to be the first telephone call reporting positive blood culture and Gram stain results (our comment: these are not provided by PhenoTest). Release of AST data (our comment: this is data from PhenoTest) did not appear to have a comparatively important impact on antimicrobial management among patients with BSI (blood stream infection).

Why did this study find that AST data is of limited importance? One of the reasons was presented by Dr. Hajo Grundmann, a presenter the ECCMID 2019 session. His message, illustrated on the slide below, was that the multiple steps are involved in the diagnostic process ranging from Diagnostic Intent to Diagnostic Validity. Because so many steps are involved, even if every step is 95% accurate, it takes only one step, for example, specimen transportation to be 75% accurate, to bring the total accuracy of decision to a mere 50%, something as good as a toss of a coin. Therefore, physicians do not trust the accuracy of the cell lab reports, simply because there are so many steps involved. As an adjunct, complimentary test, the PhenoTest does not simplify the decision process, but makes it more complex!





Source: ECCMID 2019 Conference

The situation is even worse at Emergency Departments. IDSA’s [white paper](#) outlines the following unique challenges related to Emergency Departments adoption of Rapid Diagnostics:

- Emergency Departments (ED) work in a fast-paced setting, where there are multiple competing demands on the clinician’s time and their providers must balance the risk of providing less than optimal antimicrobial use versus the need to expedite the discharge of patients in order to make space for new patients
- ED physicians see a wide range of diseases when caring for their patients, creating a major challenge when trying to keep up-to-date on advances in care. ED physicians often will not use a diagnostic test, even if it is beneficial

Here is an interesting clinical [study](#) suggesting that it takes 16 hours for an ED department to transport a blood sample. It seems to us that adopting any expensive rapid diagnostic equipment makes no sense, if transportation of the blood sample to the lab takes 16 hours.

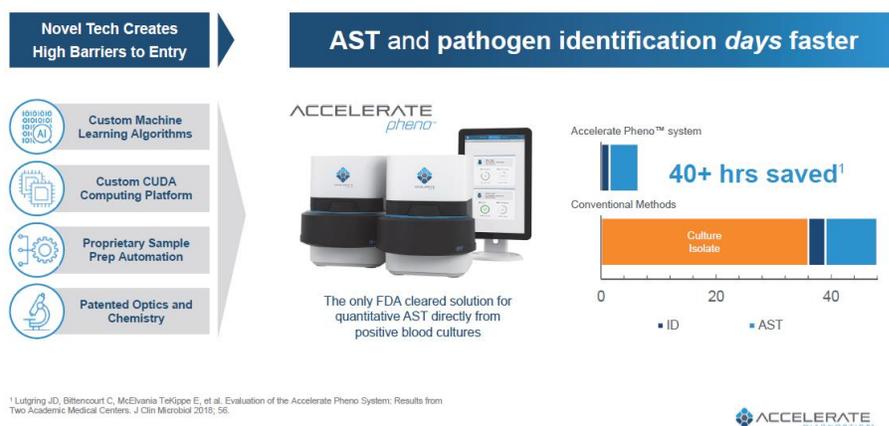


Pairing these insights about the realities of healthcare delivery with miniscule AXDX revenues makes us conclude that Pheno system is not a game changer for sepsis management.

Accelerate claims 75% faster AST results; we believe the actual time difference is less than 40% for a modern lab

In its William Blair 39th Annual Growth Stock Conference [presentation](#), AXDX claimed 75% or faster AST testing vs conventional cell culture based methods. This is illustrated below:

We Cut the Time Clinicians Have to Wait for AST by > 75%



Source: William Blair Annual Growth Conference Presentation

We examined the peer-reviewed [article](#), quoted in this slide and found an interesting author's disclosure about the control arm. Here it is:

There are features of this study that may limit generalizability. For example, identification and AST were mostly performed using the MicroScan WalkAway-96 plus system (University of Texas Southwestern [UTSW] did switch to MALDI-TOF during the study). Also, the MicroScan panels were set up and batched every morning (not put on the instrument for 24 h per day). Laboratories that release identification and AST results

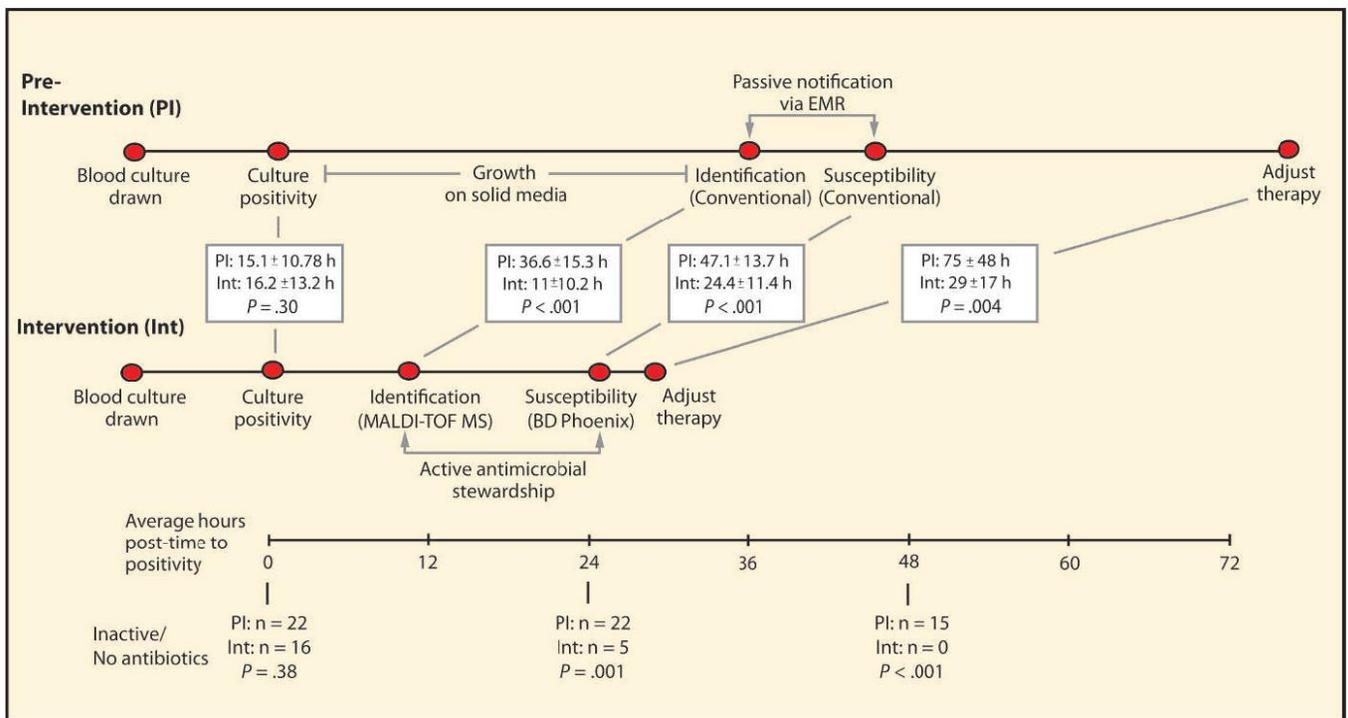


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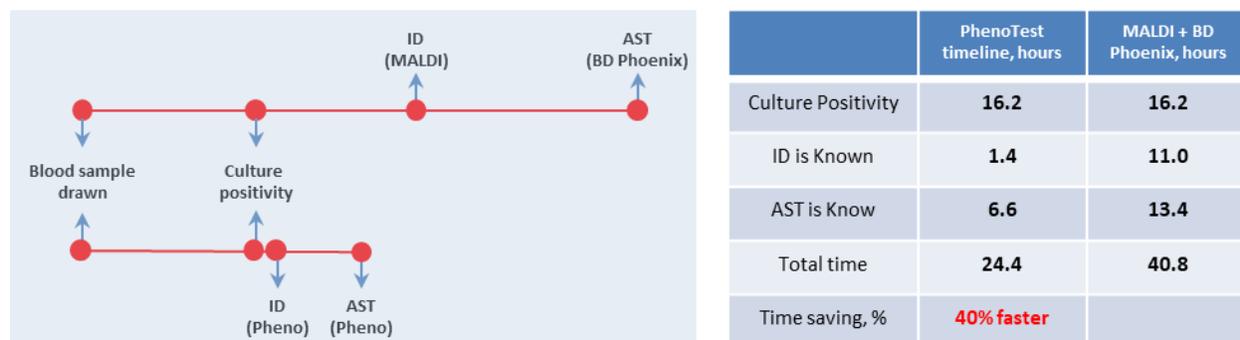
24 h per day, use MALDI-TOF immediately, and/or use rapid molecular tests would likely have very different standard-of-care times to identification and AST results.

So, how different would the standard-of-care result have been if a comparator arm released identification and AST results 24 hours per day (automated system) and used MALDI-TOF immediately? Our estimation suggests that the real time advantage of PhenoTest AST is a modest 40%, not 75%, when compared to the automated AST systems.

This [article](#) from 2012, compared “conventional” cell culture and the “newer” MALDI and BD Phoenix tests. It looks from this study that modern automated cell culture testing is done in approximately 24 hours from the time the cell culture turns positive, as shown in the diagram below. “Intervention (Int)” means blood testing processing using modern MALDI and BD Phoenix.



We used data from the diagram above to estimate the Pheno system time advantage over MALDI+BD Phoenix. In the Table and Figure below we reproduced complete timelines starting from the clinically relevant time of the blood sample drawn.



Source: WDR Research

Time from the blood sample drawn to culture positivity is 16.2h (from the [article](#)). ID time from culture positivity for Pheno system is 1.4h and time from ID to AST for Pheno system is 6.6h, both from the AXDX [website](#). Time from culture positivity to ID using MALDI is 11h and an additional time from ID to AST results using Phoenix is 13.4h (24.4-11h), both times are from the same [article](#) . Total time, relevant to a clinician, should be measured from the time when blood sample is drawn, to the time when the AST data is known. This is the truly relevant time interval, not the duration of the AST test itself.

Thus, our estimation using a corrected comparator suggests that the PhenoTest is faster by about 16h to deliver AST results, because it does skip the step of sub-cultures. Therefore, the time advantage is only 40% and not more than 75%, as [claimed](#) by AXDX.

Reagent revenues per system, carefully concealed by management, are below AXDX's already reduced expectations and trailing down

AXDX is secretive about reagent revenue, because disclosing it would reveal poor Pheno system utilization. A year ago, in the [Q218 Earnings call](#) , AXDX said this about its reagent revenue expectations.



Steve Reichling

... the reagents revenue is tracking with our expected annuity at around \$60,000 to \$80,000 per box. ... So once the system is contracted commercially, we have a three-month to four-month lag and then we have that consumable churning on

At the [Q2 2019 call](#), expectations are significantly down both in terms of revenue per system and the time lag it takes to achieve it.

Larry Mehren

...we continue to see an annuity stream in the range of \$45,000 to \$65,000 per instrument with U.S. customers at the upper end of the range and EMEA pulling down the overall average.

...Our target for the time from contract signature to go live is four to nine months.

As shown above, in the Q218 call, the lag from being contracted commercially was 3-4 months and expected annuity was \$60k-\$80k. Now, in the Q219 call, Mehren said the lag is 4-9 months, and the annuity is \$45K-\$65K. We think that within 6 months AXDX management will be forced to revise down reagent revenue expectations a second time. We built a reagent revenue model below assuming (a) newly contracted Pheno systems, in the current quarter and in the two quarters before did not generate any reagent revenue; (b) Pheno system capital sales revenue is an average of all sell-side analyst estimations; (c) AXDX receives \$200 per kit.

We examined the recently updated revenue models developed by 4 sell-side analysts in their respective analyst reports as shown below. These analysts are JP Morgan, Piper Jaffray, Craig Hallum, and BTIG.

We summarized each analyst's assumption on instrument and reagent sales during the last 6 quarters, as shown in the Table below. Instrument sales is the outright sale of the Pheno



system, while reagent sales is leasing it out. For the purpose of our further analysis we took an average of all sell-side analyst assumptions (right column).

	Instrument revenue, % of total revenue				
Period	J P Morgan	Piper Jaffray	Craig Hallum	BTIG	Average
2017	75%			28%	52%
Q1 18	33%	60%	38%	14%	36%
Q2 18	33%	63%	58%	15%	42%
Q 3 18	33%	38%	29%	5%	26%
Q 4 18	33%	30%	33%	2%	25%
Q1 19	16%	50%	25%	21%	28%

Source: Sell-side Analyst Reports

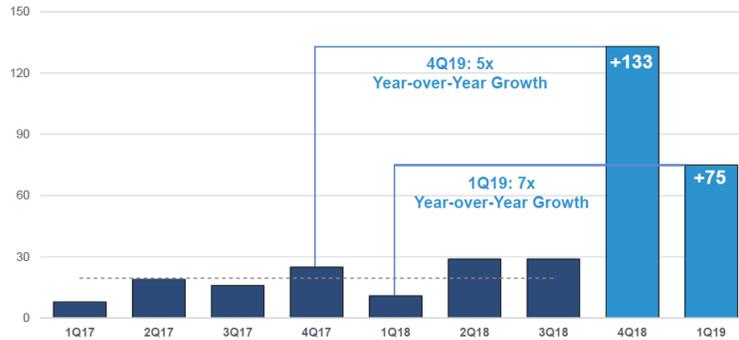
The sell-side analysts above don't say how they came to their Instrument revenue % numbers, but they have their own process. We went with their averages instead of estimating the percentage ourselves. The company is very vague about these numbers and don't share it with investors.

[Here](#) AXDX discloses its updated data on the total number of commercial systems installed world-wide at the William Blair 39th Annual Growth Stock Conference. The following is slide 11 on Market Penetration:



Market Penetration: Continuing to Build On Strong Quarterly Placement Trajectory

Global Quarterly Net Additions to Commercially Contracted Instruments:



Added 75 commercial placements in 1Q19, representing a 7x Year-over-Year growth

- Global cumulative commercial placements: 369
- Cumulative NA placements: 280
 - Added 57 placements or 11x year-over-year
- Cumulative EMEA placements: 89
 - EMEA added 18 placements or 3x year-over-year

On track to deliver 300-400 net new instrument placements in 2019

Source: William Blair Growth Conference Presentation

We reconstructed new and total commercial systems from the graph above to the total of 424 in Q2 2019 (added 55 systems from Q2 19)

quarter	new commercial placements	total commercial systems
Q2 19	55	424
Q1 19	75	369
Q4 18	133	294
Q3 18	29	161
Q2 18	29	132
Q1 18	11	103
Q4 17	26	92
Q3 17	16	66
Q2 17	20	50



Q1 17	8	30
Q4 16	22	22

To calculate the annual utilization figure for already installed systems, we made a simple assumption that no reagent revenues are generated from the systems that have been contracted in the current quarter and up to two quarters before.

We calculated the total functional system per month for every quarter, which is defined as total number of months for all functional or partially functional Pheno systems during the quarter. For example, 66 functional system-months for Q3 17 are from 22 systems contracted in Q4 16, because $66=3*22$. 90 functional system-months for Q4 17 are from 22 systems contracted in Q4 16 and 8 systems contracted in Q1 17, because $90=3*22+3*8$. And so forth.

quarter	new commercial placements	functional system-month
Q2 19	55	483
Q1 19	75	396
Q4 18	133	309
Q3 18	29	276
Q2 18	29	198
Q1 18	11	150



Q4 17	26	90
Q3 17	16	66
Q2 17	20	0
Q1 17	8	0
Q4 16	22	0

Our calculation underestimates the number of functional systems early on (before Q3 2018), because AXDX reported shorter times then for the contracted system to become fully functional.

The last step in calculating monthly utilization (number of PhenoTests per month per system) is dividing estimated reagent revenue by functional system-month. We assumed that AXDX charges \$200 per test.

Quarter	Functional system-month	Product revenue , 000	Instrument Revenue Share, %	Reagent Revenue , 000	Monthly Util-ization	12 month Reagent
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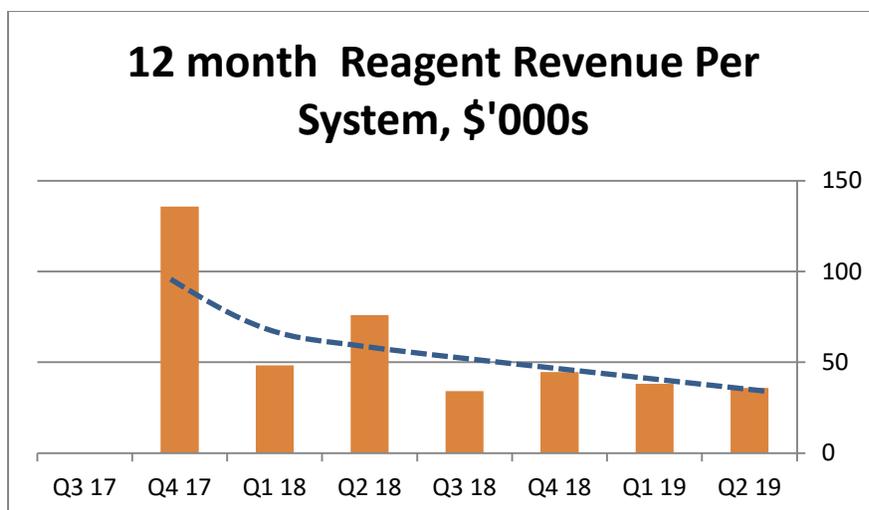


						Revenue Per System, 000
Q2 19	483	1800	28%*	1441	15	36
Q1 19	396	1750	28%	1260	16	38
Q4 18	309	1800	36%	1148	19	45
Q3 18	276	1355	42%	783	14	34
Q2 18	198	1700	26%	1254	32	76
Q1 18	150	801	25%	605	20	48
Q4 17	90	2100	52%	1019	57	136
Q3 17	66	828	100%	0	0	0
Q2 17	0	699	100%	0	0	0
Q1 17	0	530	100%	0	0	0
Q4 16	0	0	100%	0	0	0

*For Q2 19 we assumed that instrument revenue percentage was the same as Q1 19 since the sell-side analysts haven't estimated it yet.

Our modeling reveals that the average annual reagent revenues per fully installed system is below \$40,000 and is trailing down, despite management claiming it to be somewhere around \$55,000 (average of \$45,000 to \$65,000 range).





Source: WDR Research

At the [Q2 2019 call](#), a sell-side analyst also noticed the lower than projected reagent revenue per system (utilization). As she inquired below:

Julia Qin

And then lastly, in terms of utilization, I know you're maybe not ready to break out a specific revenue number. But I think, according to our model, I think the current utilization still came lower than we modeled. Just wondering, is it because of the length of time it takes for customers to go live or is it because, are you guys seeing any changes in underlying sort of customer utilization either because of your customer mix or because of other factors?

Larry Mehren

Yes, good question. As we've discussed, our expectation is to have an annuity in the range of 45,000 to 65,000 per instrument. And that's what we're seeing currently. But given the small base, quarter-on-quarter you can see some differences impacted by mix. And what I mean by that is on average, when EMEA customers go alive, they have a relatively lower annuity and then you have a little bit of a phenomenon with those that go live



faster are typically those that are independent and smaller hospitals. So they have a relatively smaller annuity. We expect that coming out of the year when the large integrated health network hospitals go live that the annuity will come back toward the middle of the range.

It appears that Mehren is not surprised with the analyst disappointed with utilization. Yet his convoluted explanation of why it has happened in Q2, contradicts “currently seeing” a \$45,000 to \$65,000 target.

Future reagent revenue is highly uncertain due to the structure of Pheno lease agreements

AXDX conveniently blames hospitals for delays of its revenue due to a longer than expected installation phase of leased Pheno systems. But what is behind these delays? Can it be just a lack of enthusiasm for the technology on a hospital site?

We think hospitals may move slowly with Pheno system utilization if contracts have no penalties for delays with installation, low reagent volumes and/or contract cancelations. AXDX is eager to sign the lease contract at a significant risk of future reagent annuity uncertainty. Why would that happen? One justification can be that short term thinking may seduce AXDX management to look good by reporting to investors the large number of units commercially contracted.

We called an AXDX Investor Relations rep and asked about the lease contract details. Below are excerpts from our call:

Q: Once the installation is up and running, is there a minimum number of tests required to be done under the reagent rental agreement?

A: Yes, there is a target, a sort of an expected volume for most of the labs. There is an expectation that they (hospitals) are a part of evaluating and determining (expected volume). So it doesn't help us at all, nor any company really, to create a situation where



a lab director is committing to something that they will never use. It really does need to be a good representation of what their volume will be.

Q: Can the hospital cancel their agreement after installation and is there a penalty?

A: I don't think there is a cancellation penalty. In some cases they may just give back the device.

Q: Why does the installation take 4-9 months?

A: This can be challenging to fully understand. When it comes to microbiology, you're basically going to perform a process. You get the results of both of those processes (new process and old process) to see how much they correlate....Ultimately, the hospital is producing a report that contains all their validation data, and they are going to submit that to the medical director of the lab. And that medical report is going to say here was our data from our verification and validation, and it matches or correlates well with our predicate methods. It is ready for routine testing. And they may find instances where it didn't match.

Q: How often does hospital validation and verification of the Pheno system fail?

A: That's a great question. There was a time that I would say with certainty that the answer was no, we have not yet failed a validation. Now, I think the number of times that we lose, you can count on one hand.

Q: Do you make any revenue while the hospital performs validation and verification testing?

A: If they are doing a strict reagent rental process, then I would say the answer is no.

We learned from this call that the AXDX reagent rental agreement is structured to give hospitals a lot of freedom. The contract does not specify a minimum number of tests and does not have a cancellation fee to cover AXDX's upfront expenses. It is up to the hospital



to decide on the target test volume later on after the internal validation phase. The hospital can return the Pheno system to AXDX any time with no penalties. Finally, AXDX doesn't make any revenue from validation studies, while providing free reagent kits for hospital.

AXDX is investing significant money into its lease model by covering the cost of leased Pheno systems, free diagnostic kits for hospital validation studies and training/support of hospital lab personnel during instrument installation. Yet, there is very little guarantee that the future reagent revenues will pay back for these initial expenses. It seems to us that the lease model may quickly become a huge liability if one of the following occurs: (i) AXDX depletes its cash reserve; (ii) negative clinical data about the Pheno system are published; (iii) a new strong competitor comes in a picture; (iv) hospitals will underutilize installed Pheno systems.

The Mayo-UCLA Study Likely Won't Show improvement in LOS (Length Of Stay) and mortality rate, both critical for Pheno system adoption

Investors eagerly wait for results of the Mayo-UCLA study to be revealed in October during IDWeek. If successful, this study may improve Pheno system adoption. Length Of Stay (LOS) improvements at the hospital is the most important factor for Pheno system adoption. In the [Q119 earnings call](#), Mehren stated:

“You will recall that length of stay is among the most important return on investment considerations for hospital administrators as it represents an opportunity to reduce non-reimbursed costs, while also freeing up beds more quickly for the next reimbursed patients.”

We agree with Mehren's above statement, but we don't expect the Mayo-UCLA study to show a significant improvement in LOS or morbidity.



This study had been completed in [November 2018](#) , but no word of it has been revealed so far. Patient follow-up, per study protocol, is 30 days or shorter, meaning that all results should have been available by January 30, 2019. The fact that the results were delayed this long suggests it isn't anything great.

Here is an excerpt from the [Q418 call](#)

Larry Mehren

While we do not control the pace or the timing of the Mayo UCLA study, we anticipate that the results will read out in the first half of this year

Nothing happened in the first half of this year. Nothing was presented at the ECCMID Congress in April 2019. Why was it decided to delay the data reporting until October? If the study showed a reduction in the mortality rate, would it be ethical waiting almost a year to reveal the study results? We don't think it would be. Because of the delay one may reasonably assume that the study did not show benefits for the sepsis mortality rate.

Management claims it does not know the study results, but we think that is highly improbable. Trustful relations and communications exist between company reps and clinicians at medical device study sites and the results have been likely known to AXDX immediately after the conclusion of the study, somewhere in February of 2019. AXDX has struggled with the adoption of its Pheno system this year and any positive insight from the study would have been very helpful.

During the Q2 2019 earnings call, AXDX made it look like getting Mayo to lease its Pheno system is evidence of great clinical results. If so, what took Mayo 6 months (from January 2019, when all study results became known to Mayo insiders to the Q2 end in June) to commit to a lease? Doesn't it make as much sense to assume that since it took AXDX management a full 6 months to convince Mayo to accept a low commitment lease, perhaps the clinical results weren't so good?



What else can we infer from the cryptic management comments about the Mayo-UCLA study? In the past, Mehren told investors that he was optimistic the Pheno system would show an improvement in LOS. AXDX would always bring up the Mayo-UCLA study as a path to generating critical evidence for clinical (mortality, morbidity) and economic (length of stay, cost) benefits of the Pheno system.

From the [Q118 Earnings call](#), on 5/9/18, Mehren stated:

“In late 2017 two institutions, the Mayo Clinic, Rochester and UCLA, secured IRB approval to conduct a randomized clinical trial investigating the efficacy and associate health economic outcomes of Pheno....

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 outcome for these critically ill patients with positive impact on mortality and morbidity length of stay stewardship and cost. We can't wait.”

From the [Q218 earnings call](#), Mehren stated:

“We believe the second of these studies to publish will be an independent multi-center government sponsored randomized prospective outcome study at Mayo Clinic, Rochester and UCLA. The studies endpoints include time to effective therapy, clinical improvement and cost.”

Mehren seems optimistic and excited in the above quotes that LOS and mortality improvements for the Pheno system will be revealed in the Mayo/UCLA study.

However, Mehren doesn't sound so optimistic in the [Q2 2019 call](#):

Will Fafinski

I guess, I'll start off with the Mayo-UCLA trials coming up here in a couple of months. I believe a lot of investors' eyes are watching that now. should we expect to see a length of



stay and mortality reduction or is time to optimal therapy really the best metric to watch here? Thanks.

Larry Mehren

You're welcome. And the metric that the study was powered to prove was time to optimal therapy. We do not know what the other endpoints will end up being, but we do know that they're not powered to statistically show a difference."

We found the above comment very telling. The analyst is probing on whether critical outcomes from the study, LOS and mortality rate will show a difference as opposed to a much less meaningful surrogate outcome of "time to optimal therapy". "Time to optimal therapy" is defined in the [study protocol](#) as "a mean time until first modification of antibiotic therapy (in hours) within 72 hours post randomization".

In 2018, before the study results were known, Larry Mehren was very excited to see improvements in mortality and length of stay from the Mayo-UCLA study. Today his excitement is gone, replaced by warnings that the study design was not powered to find the difference in LOS and mortality rates (see quote above from Q2 2019 call). To us, Mehren's defensive Q2 comments about the Mayo-UCLA study sounds as a pre-emptive justification for something he already knows.

At the 2019 ECCMID Congress, we asked industry representatives about the importance of cost saving for rapid diagnostics adoption and whether clinical trials showing LOS reduction is the proper path to success. From these responses we concluded that the demonstration of economic benefits is critical for rapid diagnostics adoption, but proving these benefits is very challenging.

From our conversation with a Beckman Coulter Rep:



The issue is that antibiotics are very expensive, so the argument is that the clinician can discharge faster, the hospital can save money, but it is a very long road to go, difficult to prove. Maybe in 10 years, if all the companies consolidate their resources, they can move the market sentiment, but it's unlikely it will happen soon.

From our conversation with a Luminex rep:

There is a lot of weight in the clinical data, but you still have a disconnect between different departments, ICU, hospital ward and the blood lab. People need to get together and it is difficult.

From our conversation with an Avails Medical rep:

Pheno is very expensive to use and the reimbursement is not high enough to cover the expense. Often you have support of the lab manager, but the hospital often does not support it, because expense is coming out of their bottom line. The system needs to fit the test flow, needs to be integrated, needs to be economical, many things are not yet working for Accelerate. Another thing is that hospitals are so afraid that they going to be sued and that is why they do not want to use new systems that do not have full proof yet.

From our conversation with a GradientTech rep:

Clinical laboratories do not have much money, they are not a rich customer. Even if you show an advantage, it takes a very long time for a hospital to approve new lab equipment. The more expensive system you have, the harder it is to sell it.

In conclusion, we think that the Mayo-UCLA study will likely fail to prove an improvement in LOS and mortality rates after the integration of the Pheno system in its diagnostic routine. What about the primary study end-point, time to optimal therapy?

We think, that the MAYO-UCLA study may still show statistically significant reduction of time to optimal therapy, something relatively easy to achieve given a 500 patient study power. We checked the results of a failed BioFire [study](#), done by the Mayo group. The



study was underpowered with only 203 patients. Despite that, the difference in time to first escalation for gram-positive infection came really close to a statistical significance with $p=0.0557$. We suspect, therefore, that it is quite possible that Mayo-UCLA finds statistical significance for, at least, some sub-groups in the study.

Will a statistically significant reduction of time to optimal therapy be critical for the adoption of the Pheno system? We believe it will not, because without proven improvements in the mortality rate and LOS, a slightly faster adjustment in the antibiotics regimen observed at the couple of premier academic hospitals under the condition of a monitored clinical trial may not even be transferrable to a typical community hospital. AXDX appears to understand this as well, downplaying the significance of Mayo-UCLA study outcomes:

From the [Q4 18 call](#)

Lawrence Mehren

The Mayo study should readout in the first half and as it relates to our placements -- while the successful outcome on the Mayo study could provide additional tailwind, it's not required for us to achieve the 300 to 400 placements that we've guided to.

AXDX's Q2 19 Analyst Call Confirms Our Bearish Thesis

In the Q219 earnings call, AXDX revealed many things about the company that we look at as very bearish.

1. Mehren hinted that with the Mayo/UCLA study, the Pheno system likely won't show an improvement in Length Of Stay (LOS) and mortality rate.
2. Reagent revenues per Pheno system were below the company's target projections.
3. Pheno system placements were below expectations, suggesting AXDX may miss the 2019 guidance of 300-400 placements.



4. EMEA (which is primarily the EU) showed a reluctance to adopt the Pheno system, despite a pressing EU priority to fight antibiotic resistance.

Points 1 and 2 have been discussed above. Below we provide details on the points 3 and 4.

Pheno system Q2 placements were below expectations, making it harder to reach the 2019 guidance of 300-400 placements

As shown in the quote above from the Q418 earnings call, AXDX has guided to 300-400 Pheno system placements in 2019. At the current rate of placements, we believe it will be very hard for AXDX to get to even the lower end of that range of 300 placements.

AXDX commercially placed the following numbers of Pheno systems in last three quarters: 133 systems in Q418; 75 systems in Q119; 55 systems in Q219. This indicates a considerable decline in Pheno system contracts over the past few quarters. So far in 2019, there have been a total of 130. That's less than Q418 alone. Could it be that all the low hanging fruit is gone, and every subsequent sale will be harder and harder to get?

With the Mayo-UCLA clinical study likely showing no significant differences in LOS and mortality, we doubt that hospitals will change their negative view of the Pheno system. AXDX needs 170 more placements to reach the minimum 2019 placement guidance of 300. That's an average of 85 per quarter for Q3 and Q4. That would be a considerable break in the current downward trend, and we believe AXDX will likely fail to deliver.

EMEA (which is primarily EU) showed a reluctance to adopt Pheno system, despite pressing EU priority to fight antibiotic resistance

In the [Q219 earnings call](#), Mehren blamed the poor performance on slow Pheno system adoption in EMEA (Europe, Middle East, Asia). EMEA is primarily Europe since there is a much smaller market right now in the Middle East and Asia.

Mehren made the following statements in the call:



“Our results for the quarter were mixed. Our 55 net new placements were up over 90% year-over-year, but came in below our expectations

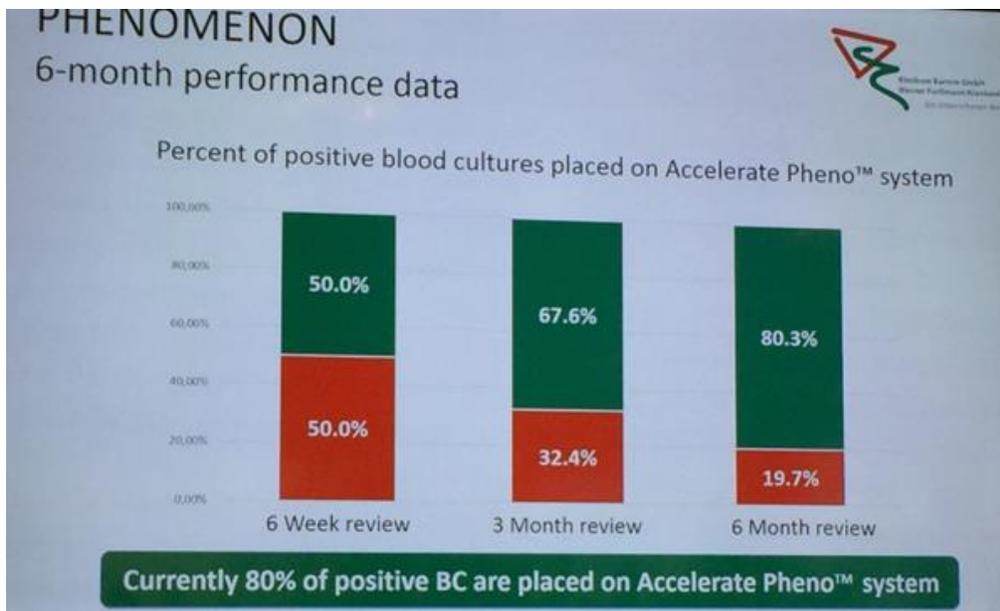
The miss was largely EMEA. And we had turnover in Germany where we had planned on several capital deals and then a large distributor deal that, while we could have closed that sooner, we held out for better pricing.”

As Mehren states above, AXDX didn't close several deals in Germany. Mehren has an excuse for why the deal didn't go through, but the fact remains that they didn't close the deal. We found it intriguing that despite [growing concerns in Europe about antibiotic resistance](#), the Pheno system, which supposedly is [designed to quickly and effectively de-escalate antibiotic regiment](#) with its anti-bacterial susceptibility test is such a hard sell in the EU. Antimicrobial resistance, aka antibiotic resistance, is a more pressing matter in the EU than in the US, and the EU is [taking action](#) to prevent it.

The fact that Pheno system adoption is slowing in the EMEA, may simply indicate the disappointment with Pheno system performance. We observed evidence of low interest of hospitals in PhenoTests during clinical studies in EU.

At the ECCMID, Dr. Wilke and Dr. Bordman reported on initial results of their PHENOMENON study using the Pheno system at Klinikum Barnim in Germany. Per study design, all positive blood cultures should have been sent both to traditional cell culture testing and to the Pheno system. The clinical study was met with a low compliance from ICU physicians and only 50% of positive blood cultures were sent to the Pheno system at week 6 after the start of the study (see the slide below). After additional efforts from Principal Investigators, the clinician's compliance, as shown in the slide by a green bar, eventually reached 80.3% at 6 months, which is still a low number for a controlled environment of a clinical study. It does not look to us that physicians were eager to know PhenoTest results, otherwise why would they be not placing positive blood cultures on Pheno systems?





Source: Slide Presentation from the ECCMID 2019

Q2 19 numbers of installed Pheno systems in EMEA countries came out below AXDX expectations, which we believe, is consistent with a lukewarm engagement of German physicians in PHENOMENON study.

Those who know the Pheno system the best do not seem to be buying.

In the investor update report from March 18, 2019 by Alexander Nowak, a Craig-Hallum sell-side analyst and a “believer” in AXDX’s product, ran a small size marketing survey among selected blood testing labs. He concludes that those who know the Pheno system the best do not seem to be buying, thus indicting the lack of product excitement on the hospital/clinician side.

Here is an excerpt with survey outcomes:

“But, we needed clarity and confidence on the annuity stream including how quickly does it ramp, are there contract minimums, pricing, etc. As a result, we concocted our current



channel check: reach out to the labs who know Pheno the best and see if they adopted Pheno following the launch of the reagent rental model. This includes labs who participated in AXDX' clinical studies. Our results were surprising...out of 15 centers with experience using Pheno, only 5 have plans to implement the system: 2 actively use it today, 2 are implementing 1H19 and 1 will "probably adopt." Among the labs not implementing Pheno (10 labs), 7 cited test cost. Other responses included lack of evidence to justify adoption, physical size of the cartridge creating capacity/logistics issues, software glitches and one lab referenced false positives and negatives as well as inconsistency with streptococcus testing.... Our concern is: if those who know Pheno the best (those who used the system previously) are not buying Pheno, then who is?"

Craig Hallum, as well as other sell-side analysts, who were initially bulls have since walked away. The only sell-side analyst bull right now is Piper Jaffray, and even they only have a \$19 PT on AXDX after the Q219 results. See the above survey outcome quote [here](#) on page 32, as well as the other sell-side reports.

No meaningful reimbursement is on the horizon for expensive PhenoTests

AXDX [charges](#) \$ 50,000 for its Pheno system and about \$200 per PhenoTest panels (list price is \$250). Currently, there is no additional reimbursement for PhenoTests and the hospital pays from the total DRG sum, meaning that an extra payment to AXDX come out of the hospital's pocket. Other rapid diagnostic companies, such as TTOO, [received](#) special add-on NTAP reimbursement, which covered 65% of the diagnostic kit cost. Given lackluster AXDX revenues, anyone would assume that NTAP reimbursement would provide a nice tailwind. Yet, it appears that AXDX management procrastinated on the NTAP application. As evident from the excerpt below, no NTAP reimbursement will be available for AXDX until at least Q4 2020, because it takes [2 extra months](#) from approval to Medicare coverage.



From the [Q2 2019 call](#):

Bill Quirk

... We did notice that the T2 was successful gainer extra add-on payments. And I know you two are pursuing that. I guess what's the latest update in that respect? Thanks.

Larry Mehren

we ... are still going to apply for NTAP program. CMS has not announced when those next round of applications are due. We expect that they'll probably do sometime in October or November. And then the approval would occur a couple of quarters after that.

AXDX is trading at a huge and unjustifiable premium vs its close comparator, T2 Biosystems (TTOO)

AXDX is hugely and un-justifiably overpriced vs T2 Biosystems (TTOO). AXDX and TTOO have a lot of similarities, which makes TTOO a valid comparator for AXDX. Indeed, both companies address sepsis, both claim faster test data, both struggle with reagent revenues. TTOO is inherently faster than AXDX, because its TTOO test is done directly from blood, while the AXDX test requires a positive blood culture sample. Why then is the market cap of AXDX so much higher than that of TTOO?

The following is a side by side comparison of TTOO and AXDX:

	TTOO (T2 Bacteria test)	AXDX (PhenoTest)
Medical condition diagnosed	Sepsis	Sepsis



Value proposition	Faster test results (2h after blood drawn)	Faster test results (20h after blood drawn)
Does it require cell culture?	No	Yes
Type of bacterial testing	ID	ID and AST
Additional Reimbursement	Yes	No
2018 Revenue, MS	10.5M	5.6M
Date of FDA approval	Q3-14 and Q2-18	Q1-17
Market cap, M\$	140	1,170
Q1-19 NC (Cash – Debt), M\$	(5)	132
Enterprise Value/Sales	14X	180X

Source: WDR Research

We first exposed TTOO with a [bearish article](#) on 3/5/19, when it has closed at \$4.29 the previous day. Today, TTOO trades at around \$1.40. In a similar way, we predict AXDX share price drop to \$6 within 6-9 months of publishing this report.

Many investors may believe in the AXDX story because its Pheno system provides not only ID but also AST data. The AST story, however, is oversimplified and overhyped, as we explained earlier in this report. There are couple of other factors that may have contributed to overpricing of AXDX. We analyze these factors below.

BioFire buyout 6 years ago does not justify AXDX's \$1B market valuation



Some investors like to compare AXDX to BioFire Diagnostics, which was acquired by BioMerieux for \$450M+debt in 2013. They add that BioFire did not even have AST data. What these optimistic investors forget is that at the time of its acquisition BioFire had almost [\\$70M](#) in annual sales. So BioMerieux was not purchasing a promising technology, but the sizable revenue at a 6.5x multiple. Realizing that AXDX struggles to break \$10M two years after a full commercial launch, one would value AXDX as a \$65M market cap business, a 95% drop from its current valuation .

Shuler's and Feinberg's stock purchases is not an indication of AXDX future success

Schuler has consistently made insider buys of AXDX, which have historically caused the stock to rally. He made a large purchase on 5/20/19 of 50K shares at \$19.03 apiece. AXDX subsequently went as high as \$24 on 7/3/19 before fading back down. AXDX had gone as low as \$15.60 on 8/9/19 after its disappointing Q219 report. On 8/12/19, Schuler purchased a smaller amount of 10K shares at \$17.45 apiece. This sparked another rally and the stock went as high as \$19.55 on 8/29/19.

Schuler and Feinberg have had some successes many years ago, such as in the 1990s, they invested in startups like [Stericycle](#) (SRCL) and Ventana. However, over the past few years they have been involved in some stinkers and penny stocks. Such as Biolase (BIOL) and Yield10 (YTEN). [Here](#) is a 2014 letter from the former CEO of Biolase, announcing his resignation. He declared:

“My decision to resign follows a protracted campaign by a majority of the Board, controlled by and acting under the direction of Oracle Partners (Oracle) (BIOLASE's largest stockholder) and Larry N. Feinberg (Oracle's Managing Partner)”

Today, [BIOL's share price](#) is at an all-time low, with a market cap of only \$20M.



Investors should think twice before following Schuler’s stock purchases as he has far from stellar track record. [This article](#) shows that he’s a 10%+ owner of many publicly traded companies which he was actively buying since 2015. The following are his major holdings:

Security	Title
YTEN / Yield10 Bioscience	10% Owner
AXDX / Accelerate Diagnostics	Director, 10% Owner
QDEL / QUIDEL	Director, 10% Owner
CAPN / Capnia	10% Owner
VRML / Vermillion	10% Owner
BIOL / Biolase	10% Owner
NEOS / Neos Therapeutics	10% Owner

Source: fintel.io

How did these stocks perform? With the exception of Quidel (QDEL), all of these stocks have a negative five years return.

Following Mr. Schuler’s stock purchases, therefore, is a risky path that we don’t recommend.



Accelerate's New Executive Hire May Indicate A Coming Change In AXDX Strategy And the Downgrade Revision Of Its Market Guidance

As we showed earlier in the report, AXDX's CEO, Larry Mehren, has done a poor job so far. Of course, it's mostly not his fault, the Pheno system is a tough sell. From evidence we've seen, we speculate that AXDX is on track to replace him. CEO replacements are a common theme with struggling companies, because it presents the opportunity to "reset" guidance, something AXDX may need to do very soon, as we discussed above.

On 8/8/19, AXDX [announced](#) that it had hired Jack Phillips for the Chief Operating Officer role, reporting to Larry Mehren. Phillips was President and CEO of Roche Diagnostics, North America. Prior to that position, he was the President of Ventana Medical Systems North America before it was acquired by Roche. This makes the story interesting, because Larry Mehren served as Senior Vice President and [Chief Financial Officer](#) of Ventana Medical Systems, Inc. from 2007 until 2008, and directly reported to Phillips. In our opinion Phillips is a higher caliber executive (former boss of Mehren, CEO of Roche North America) and he will not be taking orders from Mehren.

Jack Schuler, AXDX's [largest shareholder and a Director](#), was the Chairman of the Board of Ventana. Schuler is well acquainted with both Phillips and Mehren and no doubt was influential in hiring Phillips. We think that Schuler and the other directors are hoping that Phillips, as a higher caliber executive, will help AXDX to get out of a prolonged stagnation under the leadership of Mehren's. This may, however, open the door for significant guidance downgrade, which is scary news for investors.

\$20 Million In Quarterly Losses Is Significant, Especially As Cash Runs Out



AXDX lost \$20.8M in Q219 and \$21.5M in Q119. Clearly this level of net loss and cash burn are not sustainable for long. Right now, shareholders don't seem too concerned while the company has a considerable cash balance. AXDX reported \$137.8M in cash for Q219. However, the company is also sitting on \$125M in debt. That's quite a bit more than TTOO, which has \$50M in debt.

At the current burn rate, AXDX's cash balance will only last another six quarters. AXDX has yet to earn over \$2M in revenues for a quarter. We expect revenue to increase by many multiples into the next couple of quarters as hospitals are up and running with the Pheno systems placed in Q418. However, we don't expect it will be enough to significantly reduce the company's level of quarterly loss.

Most Sell Side Analysts Have Given Up On Accelerate

After its failed Pheno system launch, most sellside analysts have given up on AXDX and just slapped a neutral or hold rating on the company.

On 11/7/18, JPMorgan downgraded AXDX to neutral from overweight. The analyst said Q318 didn't bring what he was hoping for given "another miss and pipeline delay".

On 8/8/19, after the Q219 earnings report BTIG analyst Sean Lavin [issued](#) a report maintaining a hold rating on AXDX.

On 5/24/18, Craig-Hallum initiated AXDX with a hold rating, saying it will become attractive once expectations are significantly lowered.

Piper Jaffray is the only sell side analyst exception who still has an outperform rating on the stock. However, after Q219 results, Piper William Quirk lowered his price target to \$19 from \$22. Quirk estimated that 88 instruments would be placed in Q219, but it was only 55. He told investors in a research note: "Everything except the actual results were positive in the quarter".



AXDX shares are overpriced and we expect will be declining 70% down in the next 6-9 month.

The pressure is mounting around AXDX. With Mayo-UCLA study likely failing to show reduction in mortality and LOS, lacking NTAP reimbursement, troubling current utilization rates, and management decision to finance risky lease agreements, AXDX will continue to disappoint investors. We believe that AXDX technology is not up to the grandiose task of diagnostic revolution. Pheno's inability to replace cell culture equipment, Pheno's high rate of useless inconclusive data, an overestimated by investors clinical utility of AST, Pheno's unjustified expense over MALDI, and its user unfriendliness will eventually position AXDX as a niche diagnostic play with a fair market value of \$ 200M to \$ 300M.

