March 9, 2015

AXDX: a Near-Billion Valuation Whose Big Lie was Just Exposed by the SEC

Citron's Target: $1.00 per share within Eighteen Months

Part 1 of 2

Citron has no interest in repeating a story that has already been told. The principal points made in this report are new, and have not been published on this stock previously. We present in the company's own words, why their stock is worthless.

Three weeks ago a detailed report was published on Seeking Alpha that asked the right questions. But it was published without knowing that the answers would be posted only a week later when AXDX filed its SEC 10-K.

http://seekingalpha.com/article/2926786-accelerate-diagnostics-a-misleading-story-ripe-for-decline

What the writer of that article failed to note is that while they were busy trying to prove that Accelerate had no "accelerated" diagnostics … the SEC was already forcing the company to admit as much.

It is well known that Accelerate Diagnostics (NASDAQ:AXDX) is a controversial stock. Here are the main reasons:

- 11 years of unfulfilled promises about the same product
- No viable commercial product on the immediate horizon
- Scant R&D
- Rejected by two major pharma companies who each had exclusive rights to AXDX's platform and core technology for months -- and then walked away
- Not a single independent scientific publication on its technology -- despite over 30 papers authored by employees, and individuals compensated by the company
- A competitive landscape increasingly crowded with high-credibility and well funded competitors, each aggressively bringing new technologies to market -- many already FDA approved and/or Europe CE approval

But now, we'll step you through the sequence by which the SEC at its finest, forces the company to fess up and abandon its 10+ year misleading overreach of a story about rapid diagnostics using direct from patient blood samples.

Kudos to the Securities and Exchange Commission

In its 12+ years of publishing stock research and commentary on highly promoted and misunderstood stocks, Citron has never observed such acute and decisive subject-matter expertise from regulators as the SEC has demonstrated in AXDX. It is obvious that after 10 years of empty promises, the SEC stepped in to ask the $1 billion dollar question.

"Is your Diagnostic Test actually Accelerated?"

We see this SEC inquiry into the company's disclosures take shape in correspondence from the fall of 2014.

SEC Correspondence: Sept 9, 2014 (link)
and the **key follow-up**: **October 24, 2014** (link)

Observe in the excerpts below exactly how this exchange between the company and the regulators forces the company to come clean. Moreover, the SEC's challenges expose the company's utter disregard for truthful disclosure to its own shareholders.

The SEC publicly takes note that since 2004,AXDX has claimed to its investors that their ID/AST technology diagnoses blood pathogens and identifies antibiotic sensitivities **without requiring a positive blood culture.** Such capability, if true, would be a tremendous clinical improvement on existing methodologies, **delivering "accelerated" diagnostic and antibiotic sensitivity results in hours, rather than days in the case of serious and life threatening blood-borne infections.**

If after all these years, the ID/AST platform still needs a prerequisite **positive blood culture** before running diagnostic testing on its platform, it is Citron's opinion that the company's technology is **worthless** in the 2015 diagnostic landscape. As in bagel, zero, nada, zilch.

Citron recommends investors read the above-referenced correspondence links in entirety, but highlights the most relevant sections below. One insightful challenge is raised in Comment #3 of the 9/9/2014 filing. Referring directly to a scientific publication on the AXDX website written by a 14-year employee, the SEC writes:

We also note that your system uses a "**culture-free process**." Please tell us and in future filings disclose how you achieve cell growth **without a culture**. We note in this regard that your study indicates that certain of the bacteria being studied were subcultured on sheep's blood agar.

http://www.sec.gov/Archives/edgar/data/727207/000114420414055090/filename1.htm

In response, AXDX management provides an obtuse and confusing response. Their lack of clarity is just one example of their fast and loose play with industry jargon; but clearly they are forced to acknowledge their system does require a "**positive blood culture**."

When we state that the ID/AST System uses a **"culture-free process,"** we are referring to our system's ability to directly process a **positive blood culture**, respiratory, or other specimen without first undergoing a manual culture and isolation process.

(**Note:** Well-established tests are already available for respiratory swabs and other direct specimen types; the compelling market opportunity for the diagnostic laboratory technology industry is direct diagnosis from blood samples. This is where rapid diagnostic tools can makes a pivotal difference in the prognosis for critically ill patients suffering from sepsis, toxic shock, staph or hospital induced superbug infections.)

Then the company launches a rambling characterization of conventional laboratory processing of blood, with no reference to the current competitive landscape (as though there isn't one ... Citron will comment ...) and when they finally get to answering the question, the company says:

Instead, we plan for the operator to introduce a patient positive blood culture, respiratory, or other sample directly into our system.

 At the end of their answer, they make this extraordinary and chilling statement. Citron advises the following would an immediate red flag for **all** investors in **any** filing of **any** company, at any time, under any and all circumstances: 

We do not believe that the level of detail requested by the Staff is material to our investors, so the Company respectfully requests to not include such disclosure in its future filings.

 This is as scary as anything we've ever seen a publicly traded company state in response to an SEC question! Yet, in addition to the quote above, AXDX invokes it **no less than three other distinct times in its responses!**

From the ferocity of their follow-up, it appears the SEC was "not amused".

In its October 24 follow-on reply, the SEC pressed its issue:

> it "appears necessary for an investor to understand your use of the term **'culture-free process'"**

Finally, the company concedes the point to the SEC, while forcing investors to wait for future filings:

> We confirm that in future filings, as appropriate, we will provide explanatory **disclosure with respect to our use of the term "culture-free process."**

This company's name is "Accelerate Diagnostics" (NASDAQ:AXDX). But investors would have to read with a microscope the company's recently filed BS-loaded 10-K -- to notice that the claims of "**accelerated diagnostics" using the company's technology**, have all been **removed**.

On February 26th, AXDX Filed its 10-K and look what has been cut out

In years of previous 10-K and 10-Q filings, the company has widely used the following paragraph to describe their core business. **But now they've cut it!**

> **The Company's BACcel TM platform utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity**

This paragraph is now gone, along with ANY mention of "**culture-free" or "direct from sample" in the entire 10-K!**

How significant has that paragraph "Culture-Free Process" been to AXDX?

The phrase "Culture-Free Process" appears in:

- The company's profile description text on
  - Google Finance (link)
  - The New York Times stock listings (link)
  - NASDAQ.com (link)
  - Marketwatch.com (link)
  - MSN.com Money (link)
- The company's announcement of appearance at the J.P Morgan Healthcare conference 1/7/2015 (link)
- A company PR on PR Newswire dated 2/20/2015 announcing a $5 million grant from NIH in Morningstar (link)
- Pharmaceutical Business Review (link)
- AXDX 10-Q from 11/4/2014, 8/4/2014, 5/4/2014 (link) (link) (link)
- AXDX 10-K's from 2013, and 2012. (link) (link)
- The company's own website: http://ir.axdx.com/ (Investor Relations home page)

(**NOTE:** Synonymous language for **"culture-free process"** is **"direct from sample",** a phrase which also appears all over AXDX's websites. http://acceleratediagnostics.com/our-science/asm2014/)

Today's high ground in medical diagnostics is built upon high tech approaches to diagnosis and treatment of blood infections that specifically bypass the old-tech lab procedure of culturing blood. Blood culturing is extremely time-consuming, with no definite endpoint. 50% or more the results come back "failure to culture", and thus 8 hours can become 24 hours ... or days ... useless when a patient's life hangs is in the balance.

In contrast, "**Direct from sample**" technologies that offer diagnostic and treatment directives without these long delays is extremely valuable to healthcare providers. (See Appendix 1 for further explanation of this topic.)

The carefully crafted company perception that Accelerate's BACcel technology (now called Accelerate ID/AST) can process direct patient blood samples, and thereby avoid the time delays of positive blood cultures for their own most likely use case, **IS the foremost investment thesis for AXDX investors today**.

Lack of Analyst Coverage

It's no secret that we are in the middle of the biggest biotech / medtech boom that the markets have ever seen. Every Wall Street analyst is looking to get their foot in the door with any company that might truly deliver the latest "new new". Theranos has become the most sought after private company in the world.

Yet, AXDX, despite its often-repeated promises of a "better mousetrap", has 0 analyst coverage. Look at T2 Biosystems (TTOO). With 1/3rd the market cap, T2 has coverage from at least four firms, Goldman and Morgan included. **In Citron's 12 year history of publishing on suspect public companies, we have NEVER seen a billion dollar market cap company with zero analyst coverage, especially one in such a highly discussed field.**

We all know Wall Street loves a good story, but when it comes to AXDX, the line has to be drawn between story and fantasy.

What About Those Pilot Clinical Studies?

This SEC exchange didn't stop with the "culture" or "no culture" probe -- they pressed further, demanding clarity on the company's claims about its "pilot clinical studies".

From the 9/9/2014 SEC Correspondence:

> Your disclosure in this section refers to pilot clinical studies. Please tell us and disclose in future filings how these pilot clinical studies advance your FDA approval process.

These pilot clinical studies are limited in size and scope and are intended to provide useful insights into device efficacy. They are not intended to specifically advance our FDA approval process ...

Because pilot study data is not typically a part of an FDA submission and we do not intend to include such information in our FDA submission, we respectfully request to not disclose in our future filings how any pilot studies advance the FDA approval process.

The SEC then inquires into the independence of the published data points on the technology:

Your disclosure on page 7 indicates that three studies were conducted using the BACcel system. **Please tell us who conducted these studies and whether these "joint" studies were independent**. Please also tell us whether the referenced studies involved the pre-clinical instruments or the "proof of concept testing" that you reference...

These studies were collaborative, not independent, and were performed as part of the proof of concept testing referred to on page 6 of the Form 10-K, and not on the pre-clinical instruments.

In its October 24 reply, the SEC didn't seem amused :

To the extent that you **discuss pilot clinical trials** in your future filings, the nature and purpose of those studies should be clear to investors. Accordingly, please confirm that you will disclose your response to prior comment 10 to the extent that you include disclosure concerning pilot clinical studies.

We confirm that, to the extent we discuss pilot clinical studies in future filings, we will clarify the nature and purpose of those studies.

In addition to these questions and the ones about the phrase "culture-free process", the company "respectfully" requested to not explain further in filings responses to questions about:

- the system's ability to distinguish amongst different types of bacteria colonies
- the steps necessary prior to introducing bacterial samples into the systems' microarrays, and the time and automation of those steps
- what the system might add in the way of useful information where the identity of the pathogen is not known

In each case the company states that it does not believe the level of detail requested in the question is material to investors. 

So What About FDA Approval?

AXDX's Responses to the SEC are Starting to Read Like the Work of a Pathological Liar ... in the 5th Grade.

So now the company has clearly ditched its claim for a "culture-free" technology, but **now** states it will seek accelerated "de novo" FDA approval for its technology platform plus a test that depends on the prerequisite of positive blood culture. (See Appendix 2 for the exact quote.) But can even this vastly inferior outcome be regarded as credible ? The SEC asks:

> We note ... you anticipate initiating clinical trials for BACcel in the first half of 2015, CE mark registration in early 2015 and United States **FDA approval in early 2016**. Please tell us and revise your future filings to disclose **the basis for your belief that you will achieve those milestones as of the currently disclosed dates**. Please include in your response and disclose in future filings what steps you have taken to date to achieve those milestones and what steps remain to be taken in order to achieve those milestones including whether you will seek FDA registration and approval of your proposed clinical trials.

"The exact regulatory path for the AST portion of our system and positive blood culture test kit is still being evaluated by the Company and is the subject of ongoing discussion with the FDA.

... The FDA approval process for our ID/AST System and positive blood culture test kit will require a clinical study that supports statistical equivalency with established clinical standards for both identification and susceptibility.

... We anticipate initiating clinical trials for the ID/AST System and positive blood culture test kit in the first half of 2015, CE mark registration in early 2015 and FDA approval in early 2016."

But when AXDX filed their 10-K, they had advanced their claimed approval date to 2015. Responding to the demand for milestones, the company issued a plan so severely messed up we had to reprint it (see below).

Oh, and just one more thing: **Not one single penny spent on clinical trials in 2014!** We are not making this up, either**.** From the just-filed 2014 10-K (link):

Clinical Trial Agreements

The Company has entered into master agreements with clinical trial sites in which we typically pay a set amount for start-up costs and then pay for work performed. **No amounts have been incurred for these arrangements through December 31, 2014.**

Let's get this straight: The company acknowledges that :

- A formal clinical trial of ID/AST will be required
- The clinical trial plan has not yet been filed
- Not one penny was spent on clinical trials in 2014
- Their own pilot clinical studies provide no independent basis for required clinical trials

Regardless, the company asserts that it **will** gain FDA approval in 2015. Really ???

Although we currently do not have any products on the market, we anticipate that the ID/AST System will receive FDA approval in calendar year 2015.

Proposed AXDX Milestones for 2015 FDA Approval

(Editor's Note: Citron has copied and pasted this set of milestones verbatim from AXDX's just-filed 10-K -- highlighted yellow is our commentary)

As of December 31, 2014 we have completed the following steps toward our goal of obtaining regulatory approvals for E.U. and U.S. launches of the ID/AST System and positive blood culture test kit:

- design of the final ID/AST System and positive blood culture test kit;
- meeting with the FDA to discuss the regulatory approval path for the ID/AST System and positive blood culture test kit;
- design of the U.S. clinical study;
- selection of clinical trial sites;
- obtain ISO13485 certification based on the establishment and audit of a product quality system; and
- building good manufacturing practice (GMP) manufacturing and test facilities.

Key remaining steps toward obtaining a CE-mark for commercialization in the E.U., anticipated for the first half of 2015, and **upon obtaining FDA approval commercializing the product in the U.S., include:**

- completing product technical files and providing a self-declaration of conformity to our E.U. authorized representative after which CE mark will be obtained;
- the execution of the U.S. clinical trials**; <--- Approval of FDA first, then clinical trials?**
- preparation of the FDA submission following the clinical trials; and **<--- Ditto: So first they obtain "FDA approval commercializing the product", and THEN they execute the clinical trials ?**
- obtaining a positive review of this submission from the FDA**. <--- Ditto, but Citron observes the FDA will probably want do the review this before issuing clearance...**

From the **AXDX 10-K for 2014 Page 9 (** link)

Reality Check: Sounds like a plan! Except .. how can this plan possibly be accomplished in less than 2.5 or 3 years ?

Two major competitors, T2 and Abbott IRIDICA provide useful timeline comparisons. T2 began clinical trials in 2012, and received FDA approval in September and December 2014. Abbott's IRIDICA, which is currently approved for use in Europe, has begun US clinical trials, with approval anticipated in 2017.

It is impossible to ignore that this entire FDA approval plan puts the company on a course to receive approval for a product, which to the extent **it depends upon cultured blood** as a starting point for its analysis, the diagnostics market neither needs nor wants. It is Citron's opinion that this plan is intended to defend the stock price by misleading investors, rather than bring a legitimate product to the medical diagnostics market.

All of the company's bullshit, which is obvious to the SEC, and investors are left to puzzle out, was figured out by past potential industry partners. We could have read between the lines:

Becton Dickinson and Novartis Both Previously Studied BACcel ... and Both Walked Away.

September 2009: Despite the impressive sounding results of studies published in 2008, more than a year after the its publication, and after spending nine months evaluating the BACcel platform, Becton Dickinson (BDX) (market cap 28 billion) passed on the opportunity to license AXDX's technology.

> 12/14/2007 Becton Dickinson May Collaborate with Acceler8
> https://www.genomeweb.com/becton-dickinson-may-collaborate-accelr8-rapid-dx-platform
>
> 9/25/2009 Becton Dickinson walks away:
> http://www.businesswire.com/news/home/20090925005538/en/Accelr8-Becton-Dickinson-Conclude-Technical-Development-Project#.VPd7nfnF98F

September 2011: Four months after yet another published study on BACcel, Novartis (NOV) (market cap 22 billion) passed on the opportunity to license BACcel, after spending 16 months evaluating it.

> 7/25/2011 Novartis expands collaboration:
> http://www.businesswire.com/news/home/20110725005577/en/Accelr8-Announces-Continuation-Expansion-BACcel%E2%84%A2-Development-Collaboration#.VPW-0fnF98E
>
> 10/13/2011 Novartis walks away:
> https://www.genomeweb.com/mdx/novartis-deal-evaluate-accelr8s-baccel-platform-expires-without-further-extensio

AXDX's R&D Expense

Meanwhile, here's the total R&D expense as filed in AXDX's 10-K's for in the last seven years. Is this really the commitment of a supremely qualified innovator to dominate this space?

2008	1,001,000
2009	746,000
2010	502,000
2011	455,000
2012	432,000
2013	10,673,000
2014	8,125,000

Editors Note: It is important for all who trade in the stock of Accelerate Diagnostics that Citron warns and understands about its trading dynamics. AXDX is a heavily shorted, and a relatively tightly held name that purports to be developing breakthrough technology in a hot industry, so short term movement in the stock may be somewhat distorted. But, unless this company can find a way to change 10 years of misleading messages to the investing public into a better mousetrap built from scratch, against formidable competition, while fighting off the inevitable class action lawsuits, this stock is going to $1.00 in eighteen months. If the stock were more widely held, with analyst coverage and increased liquidity, our target would be $1.00 in three months.

Because of the extreme disclosure deficiencies documented below, it is Citron's opinion that this company remains extremely vulnerable to regulatory intervention from the SEC at any time.

Conclusion

Looks to us like the above-referenced pointed inquiries from the SEC demonstrate they've figured out ***exactly*** what the game is here. Their job however, isn't to prevent smoke-and-mirrors from being sold to the public. They can only make sure that companies peddling this shit disclose exactly what they are doing, in black and white.

This company's current track to FDA approval isn't intended to create a saleable product; any diagnostic like their current proposal, that depends upon prerequisite blood culture, is DOA in the marketplace. So they're going to make a major investment in a set of clinical trials suitable for an FDA approval process, **purely to continue the smokescreen that the stock is hot buy?**

This approval process has taken credible and comparable competitors 3 years, but AXDX claims it will complete it in 2015, despite not having started the clinical trial yet. Good luck with that!

If approved, this product, which requires pre-cultured blood, will have zero market traction. **Will AXDX will be obliged to hire a sales force to try to sell it, all of which will be sunk cost, just to keep up the charade?** By the time this company might legitimately earn approval for a culture-free diagnostic for important infections, it will be swarmed under by competition.

Kudos to the SEC, and cautious Investing to All

 **Stay tuned for part 2, in which we dissect the new set of lies from AXDX in their dishonest portrayal of the competitive landscape, and how they mischaracterize product they allegedly will bring to market some day in the future.**

(supplementary appendix material below)

Appendix 1:

"Positive Blood Culture" vs "Direct Patient Blood Sample"

What Investors Need to Know:

The technical issue investors need to focus on is really quite straightforward...except when you read the company's bafflegab.

When a seriously ill patient seeks medical care for an systemic infection -- via the ER, a doctor's office or clinic -- the ideal scenario would be a rapid diagnostic test which identifies the pathogen as well as the most effective antibiotic to treat the infection. For example, in recent years a rapid antigen test direct from a throat swab resolves most uncertainty about whether common severe throat infections are "strep".

But for several types of serious blood infections, (including for example, toxic shock, sepsis, staph and other hospital-induced infections) no decisive rapid clinical alternative has been available. The standard of care has been to culture blood from a blood draw in a clinical lab -- attempting to grow the pathogen causing the patient's illness, first to identify it, then further testing the cultured growth for antibiotic susceptibility or resistance.

The problem is that this process runs a long and indeterminate course. A disturbingly high percentage of cultures, approaching 50% for some infections, fail to culture decisively; the blood pathogen fails to grow in an incubator. This point is critical because failure-to-culture results (e.g. false negatives) extend the time needed to positively identify the pathogen for an uncertain span of hours or days. Waiting out this interval -- hour by hour -- day by day -- doesn't ever give assurance that a decisive pathogen ID or treatment plan will emerge.

Meanwhile, the physician treating a critically ill infected patient often doesn't have time to wait to initiate treatment. For medical practitioners dealing with critically ill patients, the risks of waiting to begin treatment often outweigh the concerns about prescribing the optimal drug. Without a clear treatment indicator, the clinician will be forced by the urgency of the illness to prescribe a broad spectrum antibiotic, which might not be the best option to treat the specific pathogen, and might not improve the patient's condition at all. So in addition to sub-optimal clinical outcomes, the overuse of broad-spectrum antibiotics is creating increasing dangers of spawning superbugs.

So AXDX describes current clinical practice as taking "hours or days", but when it suits their purposes, they minimize the obstacles of needing positive blood cultures:

Blood culture is a routine laboratory process which determines negative from positive samples through incubation and takes on average 8 hours to complete.

They present no data to support this claim; no statements proving that their technology makes their culturing of blood any faster or more accurate than current clinical practice as explained above. (And of course, they ignore all the competitive "Direct from Sample" platforms.)

But the above-described clinical drawbacks -- culturing blood on an uncertain timeline -- remains the **primary driver** for the market for advanced diagnostics technology.

To claim they have a 13-hour solution (they state that is what they are applying to FDA for de novo clearance for), the company has to try to bend language to sweep under the rug the massive problem abundantly obvious in clinical practice already: the failure to culture -- false negatives, which set the process of diagnosis and treatment back hours or even days.....

Thus after 10 years' sound and fury, the product and test kit they are now proposing to submit to FDA, requires **cultured blood**, with all its clinical uncertainties. After all this time, this is simply not a viable competitor any more.

Appendix 2: A More Complete Excerpt from AXDX Answers to SEC on the Topic of "Blood Culture"

For the purposes of clarity and continuity of our story, we excerpted direct statements for relevance to the sequence of topics discussed. But AXDX's full explanation of the critical question -- are they applying for clearance for a "proprietary culture-free process" -- speaks volumes, although it is written in a convoluted style that conflates numerous points.

So if you've read this far, here is the key passage, straight from **Page 8** of their just-filed 10-K:

> ***Accelerate ID/AST System & Positive Blood Culture Test Kit***
>
> The ID/AST System features walk-away automation and consists of a fixed instrument and proprietary single-use test kit. The instrument consists of module(s) connected to a single analysis computer, which allows hospitals to acquire various numbers of modules to address their particular test volume. In order to run a patient sample on the Accelerate ID/AST System the technician would pipette the patient sample into our system, insert the test kit, and initiate the run. In the case of our initial test a positive blood culture sample is introduced to the system through pipetting directly from the blood culture bottle into our test kit. Blood culture is a routine laboratory process which determines negative from positive samples through incubation and takes **on average 8 hours** to complete. After approximately **one hour** from sample introduction, an ID result would be available, and after an additional **four hours** the AST would also be complete.

So that's **13 hours**, **not 5**, and if -- (and that's a **big if** -- to be proved through clinical trials which are yet to begin) **and only if -- after 8 hours -- a positive blood culture has been successfully achieved** -- and in fact it's the **correct positive blood culture** populated with the patient's pathogen(s). Otherwise, the process stretches longer, just like the "routine laboratory process" they state it is. The obligation is on AXDX to **prove** this in its yet-to-begin clinical trials.

The company has left the entire topic of failure-to-culture out of the discussion. Investors might overlook this, but no clinician can or will, nor will the FDA. Approval for a process dependent on blood culture will not give AXDX any ability to sell this platform for "Direct from Sample" -- that protocol and any accessories, would require their own separate clinical trials.