BTIG

Equity Research
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Medical Technology

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T2 Biosystems, Inc.

Initiating Coverage with Neutral Rating; Like the Technology, but Fear T2Candida Commercialization

We are bullish on T2's technology and the potential market for T2Bacteria, but we believe the commercialization of T2Candida will be challenging.

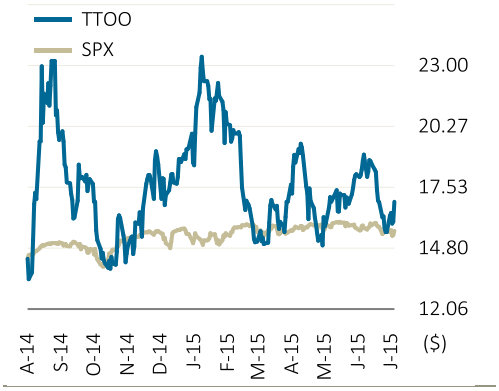
- **We would want the T2Candida/T2Bacteria assays available if we were in the hospital and at risk for sepsis.** Current diagnostics for the detection and identification of sepsis-causing organisms are inadequate due to the time required for an organism to reach a detectable concentration. By detecting and identifying these pathogens within a few hours of a blood draw vs. the ~10-12 hours or even days required now, T2's platform can enable physicians to deliver more timely and effective drug therapy, in our view.
- **Sepsis is expensive and mortality rates hover above 20%.** Since it can take anywhere from ~10-12 hrs to a few days for bloodstream pathogens to be identified, most clinicians administer empiric antibacterials/antifungals prior to identifying the organism causing the infection. However, in ~20-40% of cases, this therapy is ineffective. Numerous studies support the premise that delays in appropriate antibacterial/antifungal therapy increase mortality. By identifying pathogens earlier and reducing the time to appropriate therapy, T2Candida and T2Bacteria can save lives and money, we believe.
- **T2's pipeline, notably the T2Bacteria Panel, looks very promising;** however, currently T2Candida is the company's only approved test.
- **And our T2Candida channel checks came back lukewarm,** with many infectious disease docs and microbiology lab directors unlikely to adopt the panel for numerous reasons. We view the test's price (~$250), the belief that *Candida* is not a major issue, and uncertainty among docs of how to adopt such a test in a cost-effective manner (and without clinical utility studies) as significant near-term hurdles.

TTOO $16.10

NEUTRAL

52 week range	$13.40 - $23.40
Market Cap (m)	$335

Price Performance



Source: IDC

Estimates

	1Q14 A	2Q14 A	3Q14 A	4Q14 A	FY14 A	1Q15 A	2Q15 E	3Q15 E	4Q15 E	FY15 E	FY16 E
Sales	0	0	0	0	0	0	0	0	1	1	4
Gross Margin (%)	-	-	-	-	-	-	10.0%	15.0%	20.0%	15.7%	32.6%
EBIT	(7)	(7)	(8)	(9)	(31)	(10)	(11)	(12)	(12)	(45)	(55)
Net Income (Adj.)	(9)	(9)	(9)	(9)	(36)	(11)	(11)	(12)	(13)	(47)	(60)
Diluted EPS (GAAP)	(6.25)	0.00	(0.71)	(0.45)	(4.15)	(0.53)	(0.57)	(0.60)	(0.63)	(2.34)	(2.60)

Source: BTIG Research Estimates and Company Documents ($ in millions, except per share amount)
TTOO US Equity

Our T2 Biosystems Thesis

T2 Biosystems is an early commercialization-stage diagnostics company. T2 received FDA clearance for its first two products, the T2Dx Instrument and T2Candida Panel, in September 2014 and recently commenced commercialization efforts in the U.S. The T2Candida Panel can be used to identify the five clinically relevant species of *Candida*, which is a fungal pathogen known to cause sepsis, within 3-5 hours of a blood draw. T2 has also developed the T2Bacteria Panel, which is designed to detect within 3-5 hours of a blood draw the bacterial pathogens associated with sepsis that first-line empiric antibiotics often fail to effectively treat. Despite our belief that the ability to detect and identify sepsis-causing pathogens within 3-5 hours of a blood draw enables physicians to deliver more timely and effective drug therapy, our extensive channel checks suggest that early T2Candida commercialization will be very challenging. We expect the test's price (~$250), the belief that *Candida* is not a major issue, and uncertainty among docs of how to adopt such a test in a cost-effective manner (and without clinical utility studies) to be significant near-term hurdles and while these impediments may be overcome, we believe it will take some time. Finally, while we are far more optimistic on the market opportunity for T2Bacteria, we don't expect this panel to reach the U.S. market until early 2017.

The Positives

We believe T2's ability to detect and identify sepsis-causing pathogens within 3-5 hours of a blood draw addresses an important unmet need within microbiology testing today.

Despite their limitations, blood cultures are considered the "gold standard" for the detection of microbial pathogens in the bloodstream. When it comes to sepsis, the most significant limitation of blood culture is level of detection and thus time, since it can take ~8-12 hours or even several days for an organism to grow to a detectable concentration. T2's first FDA-approved assay is the T2Candida Panel, which can detect and identify *Candida* at limits of detection as low as ~1-3 CFU/mL within ~3-5 hours of a blood draw. Next up is T2's T2Bacteria Panel, which has been developed to detect and identify the major bacterial pathogens associated with sepsis that are frequently not covered by first-line antibiotics within 3-5 hours of a blood draw.

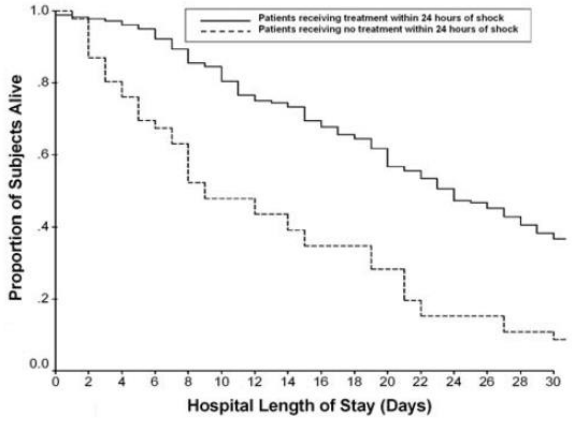
Knowing a pathogen's identification within a few hours of a blood draw should help physicians select more effective empiric drug therapy in a shorter period of time than what occurs today.

Published data illustrates that a strong relationship between delays in the administration of effective antimicrobial therapy and in-hospital mortality exists among critically ill patients with sepsis. A 2006 study published in *Critical Care* showed that the "initiation of effective antimicrobial therapy within the first hour following onset of septic shock-related hypotension was associated with 79.9% survival to hospital discharge" and that "for every additional hour to effective antimicrobial initiation in the first 6 hours after hypotension onset,

survival dropped an average of 7.6%". The study's authors also looked at other management variables, including the effectiveness of initial antimicrobial therapy, the choice and magnitude of early fluid resuscitation, single vs. multiple drug class antimicrobial therapy, and choice and speed of initiation of initial vasopressor/inotropic support and notably, the time to effective antimicrobial therapy was most strongly associated with patient outcomes.

As with antibacterials, various studies have demonstrated that the delayed administration of appropriate antifungal therapy is associated with higher mortality among patients with septic shock attributed to *Candida* infection. A 2012 study published in *Clinical Infectious Diseases* looked retrospectively at 242 patients with septic shock and positive blood culture for *Candida* and found that the hospital mortality rate for patients having adequate source control and antifungal therapy administered with 24 hours of the onset of the shock was 52.8% vs. 97.6% in patients who did not have these two goals attained. In this study, ~18% of patients received no antifungal therapy prior to their death due to delayed recognition of the presence of fungal infection. Among these patients, the average time period between the onset of septic shock and death was 48 hours vs. an average time period of 56 hours between blood draw/culture (that subsequently grew a *Candida* species) and the reporting of a positive culture. As shown in the graph below, the ~80% of patients who received appropriate antifungal therapy within 24 hours of the onset of shock had a significantly greater likelihood of survival compared to patients not receiving appropriate therapy within 24 hours.

Exhibit 1: Kaplan-Meier curves comparing patients who received antifungal therapy within 24 hours of the onset of septic shock and those who received no antifungal therapy within 24 hours of the onset of septic shock (P < .001; log-rank test).



Source: Septic Shock Attributed to Candida Infection: Importance of Empiric Therapy and Source Control, Clinical Infectious Diseases, 2012

As a result of various studies such as the ones described above and current infectious disease guidelines, most patients are given empiric, broad-spectrum antibiotic therapy when a bloodstream infection is first suspected. However, this empiric therapy is only effective ~60-80% of the time and clinicians are essentially "shooting blind," since the pathogen's preliminary identification is unknown for at least ~10-12 hours post-blood draw. Of the ~30% of the time when empiric therapy is not effective, we believe that fungus is the cause about a quarter of the time. By identifying sepsis-causing pathogens within a

few hours of a blood draw vs. the ~10-12 hrs or even days required now, we believe T2's platform can help physicians select more effective empiric antibiotic or antifungal therapy in a shorter period of time than what occurs today and help lower mortality caused by a delay in the administration of appropriate therapy.

Despite the seemingly low prevalence of *Candida* infection, its associated costs are significant.

Per company estimates, over 1.6 million individuals are diagnosed with sepsis each year, 1.35 million of whom are at high risk for infection due to their suppressed immune system or presence in a critical care unit. As discussed above, ~20-40% of these patients will not respond to empiric broad-spectrum antibiotic treatment. T2 estimates that ~25% of these non-responders have a *Candida* infection, with the remaining 75% having a bacterial infection. Though this ~25% seemed high to us initially, various studies have in fact reported that the prevalence of *Candida* ranges from 2-11% in high-risk patient populations, making *Candida* among the top 5-10 pathogens causing nosocomial bloodstream infections today. Furthermore, in line with the papers we came across, the infectious disease physicians we surveyed reported an average *Candida* prevalence of 8% among their high-risk patients.

The exact costs associated with a patient infected with *Candida* vary widely based on length of stay, length of ICU stay, how significant a patient's other comorbidities are, etc. However, based on all of the studies we reviewed, we estimate the incremental cost of a patient with *Candida* infection ranges between ~$20,000 - $75,000 per patient. Since the time to effective antifungal therapy correlates with reductions in both mortality and length of stay, we believe the rapid detection and identification of *Candida* via the T2Candida panel could lead to meaningful cost savings for hospitals.

Additionally, the epidemiology of candidemia is changing and antifungal resistance has become an issue.

Published data indicates that the mortality rate among patients with a bloodstream infection caused by *Candida* ranges from 30-50%. We believe the mortality rate associated with *Candida* infection hovers in this range due to three main factors: 1) typically, *Candida* patients are very sick and have multiple other comorbidities, 2) the delayed administration of empiric antifungal therapy, and 3) the delayed administration of appropriate antifungal therapy, as the resistance of some *Candida* species to the most commonly used empiric antifungal, fluconazole, has grown. Additionally, we note that *C. glabrata*, one of the more resistant *Candida* species, sometimes requires more than five days of growth to reach a detectable concentration and as a result is sometimes missed by blood culture altogether.

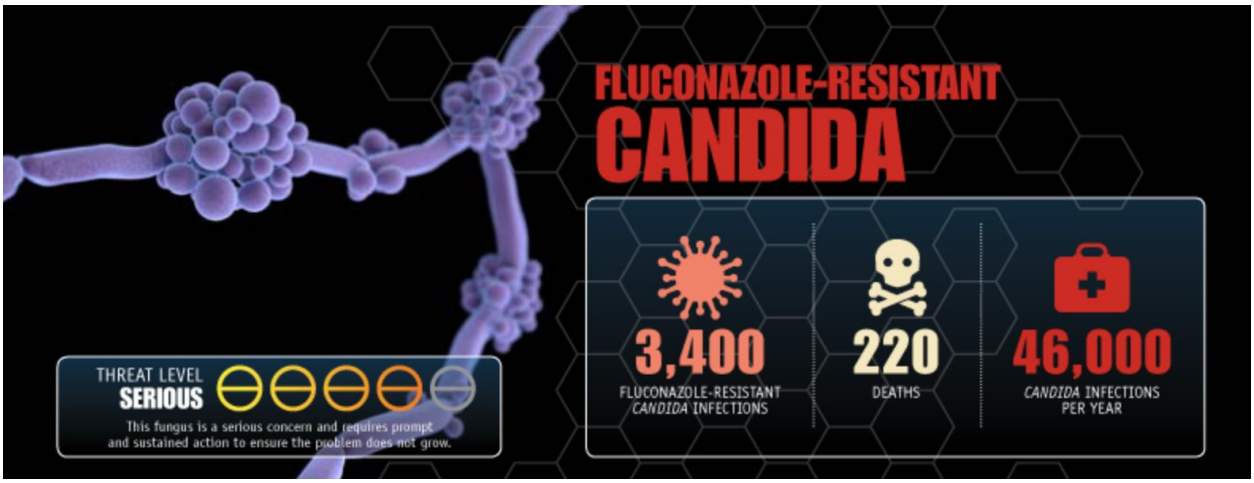
C. albicans is the most common species of *Candida* and is generally susceptible to fluconazole; however, over the past few years the epidemiology of candidemia has changed, with an increasing number of bloodstream infections caused by *non-albicans Candida* species, such as *C. glabrata*, *C. krusei*, *C. parapsilosis*, and *C. tropicalis*.

Per Infectious Diseases Society of America (IDSA) guidelines, the choice of empiric antifungal therapy should be based on the local pattern of the most prevalent *Candida* species and any recent exposure to antifungal drugs. The

use of either fluconazole or an echinocandin (typically more expensive, but preferred in patients with severe illness, especially those who have recently been treated with antifungal agents, or if *C.glabrata* infection is suspected from earlier culture data) is currently recommended. In 2013, the Centers for Disease Control and Prevention (CDC) published a report that outlined the top 18 drug-resistant threats to the United States and this list included Fluconazole-Resistant *Candida.*

T2Candida's ability to rapidly identify the species of *Candida* that is causing an infection or to rule out a suspected *Candida* infection should lead to more appropriate antifungal use and a reduction in the use of inappropriate antifungal therapy in our view, both of which are increasingly important as antimicrobial resistance rises.

Exhibit 2: Fluconazole-Resistant Candida



Source: CDC, 2011

While it is difficult to discern mortality directly attributable to *Candida* vs. candidemic patients' underlying disease/condition (and many think it is almost entirely the latter), data suggests that ~30% is in fact directly attributable to candidemia.

Various studies have sought to determine mortality directly attributable to *Candida* vs. underlying disease. Though there is not an abundance of studies with matched patient cohorts, a systematic review of matched cohort and case-control studies was published in the *European Journal of Clinical Microbiology Infectious Diseases* in 2006. In addition to mortality, secondary variables examined included length and cost of hospital stay. The study's authors concluded that candidemia is associated with considerable mortality that is attributed at least to some degree to candidemia and not only to the presence of another comorbidity. The range of mortality attributable to candidemia was 5% - 71%, with an average of 31% across the reviewed studies. Furthermore, evidence from the studies suggested patients with candidemia have longer hospital stays compared with matched controls (in one study the length of hospital stay was more than double for the matched candidemia patients). These extended hospital stays were also associated with increased hospital charges, which were double or even more for candidemia patients in some of the studies.

We believe that T2's published T2Candida data is compelling and that the T2Bacteria Panel should have a similar level of detection.

The detection of organisms at very low levels of concentration is challenging and a big part of why blood culture remains standard of care despite its limitations. Since an organism must typically grow to a higher concentration than is present in the blood stream upon a blood draw, it can take hours or days before a blood culture turns positive. The prospective arm of T2's direcT2 pivotal clinical trial included ~1,500 patient samples and in the overall trial the T2Candida Panel and T2Dx instrument demonstrated 91.1% sensitivity and 99.4% specificity at a level of detection between 1 – 3 CFU/mL. The speed to a species-specific positive result with T2Candida was 4.4 hours vs. 129 hours with blood culture and a negative result with T2Candida was obtained in 4.2 hours vs. 120 hours with blood culture. We view this data as very compelling.

Per our diligence, though many companies are trying to develop and/or commercialize assays that can detect pathogens prior to positive blood (please see our Competition section below for more details), T2's platform appears to have the lowest demonstrated level of detection. Based on the principles of the T2MR technology, we expect the T2Bacteria Panel to be able to detect and identify various bacterial species in the same timeframe as T2Candida and with a similar level of sensitivity and specificity.

Sizable market opportunity, interest in T2's Bacteria Panel seems high; T2HemoStat and T2Lyme could also matter.

T2 has estimated its initial annual addressable market opportunity for sepsis (T2Candida and T2Bacteria on the T2Dx instrument), hemostasis (T2HemoStat instrument and T2Stat assay, both in development), and Lyme disease (T2Lyme test in development, to be run on the T2Dx instrument) at over $3.7 billion in the U.S. alone. Within the sepsis market in the U.S., the company estimates that there are approximately 6.75 million critical care and immunocompromised patients who present with symptoms and are at high risk for a bloodstream infection who would be appropriate to be tested by the T2Candida Panel. These patients, plus another ~2M additional patients who receive treatment in the emergency room setting and are also highly susceptible to bacterial infections, would likely be appropriate to be tested by the T2Bacteria Panel. Despite lukewarm interest in the T2Candida panel (we discuss this in more detail below) among the physicians we surveyed, interest in the T2Bacteria was more favorable. On a scale of 1 to 5 (1 being very unlikely to adopt the Panel and 5 being very likely to adopt the Panel), ~90% of the infectious disease physicians answered "4" or "5," with an average of 4.4 out of 5 (vs. only 60% of the same group of docs ranking T2Candida as a "4" or "5" and the average response on likelihood of adopting T2Candida coming in at a 3.6 out of 5). Among lab directors, T2Bacteria also scored much higher than T2Candida, with an average of 3.7 out of 5 for likelihood of adopting T2Bacteria vs. an average of 2.1 out of 5 for T2Candida.

T2 is also working on a hemostasis instrument and diagnostic panel (T2HemoStat and T2Stat) as well as a panel for Lyme disease. Within the hemostasis market, for trauma alone, the company estimates that there are

over 10M patients in the U.S. annually who present with symptoms of impaired hemostasis. For Lyme, the company estimates that the majority of the ~3.4M tests run annually would be appropriate for testing with the T2Lyme Panel.

Of these panels we see T2Bacteria as most valuable and containing the least development risk. On T2Candida, we are nervous about adoption, particularly at its current price point. We have high hopes for both T2Stat and T2Lyme, but need to see more data before feeling confident in accurately sizing their respective market opportunities. Based on our diligence and review of current data, we would estimate T2's market opportunity closer to $2B (~9M T2Bacteria tests at a price point of $150/test; ~3M T2Candida tests at $50/test, ~10M T2Stat tests at $20/test; and ~2M T2Lyme tests at $200/test), which is still very sizable.

Hospitals are incentivized to adopt technologies that can help reduce healthcare-associated infections, improve outcomes and save money; this could serve as a tailwind for both T2Candida and T2Bacteria.

Cost containment, risk-sharing, and outcome-based treatment and reimbursement are important aspects of healthcare reform today. With sepsis mortality rates north of 20%, the costs associated with sepsis representing a large chunk of the U.S. annual healthcare spend, and a reduction in the use of antibiotics a clear focus in our country due to resistance, it seems logical that T2's T2Candida and T2Bacteria panels would be received warmly by hospitals and physicians based on published data that supports lower mortality rates and cost savings when appropriate antibacterial and antifungal therapy is used within hours of symptoms vs. days. While one can argue that the current paradigm of initial empiric broad-spectrum therapy followed by appropriate therapy is "good enough", we don't think sepsis mortality rates would be as high as they are if this truly were the case.

Furthermore, as part of the Affordable Care Act, several changes were made to Medicare hospital payment policy in efforts to reduce wasteful spending and improve the value of hospital services. A payment adjustment for hospital-acquired conditions is one of these changes, and beginning in FY2015, hospitals scoring in the top quartile for the rate of hospital-acquired conditions vs. the national average will have their Medicare payments reduced by 1% for all DRGs. Per the CDC, primary bloodstream infections are the fifth most common type of healthcare-associated infection within U.S. hospitals, with candidemia, the most common form of invasive candidiasis, being one of the most common bloodstream infections in the United States. We believe the ACA and this change in policy should give hospitals and clinicians an additional incentive to adopt technologies such as T2's that can detect and identify pathogens more rapidly, thus enabling faster and more effective treatment.

The potential broad applicability of T2's T2MR platform makes the company an attractive acquisition candidate in our view.

The ability to directly detect a variety of targets (DNA, pathogen cells, proteins, etc.) within multiple sample types (whole blood, plasma, serum,

saliva, sputum, and urine) suggests that T2's market opportunity could extend far beyond the company's current programs, and numerous studies have shown the potential applicability of T2's T2MR platform both within and outside of the in vitro diagnostics market.

Within sepsis, which is T2's initial focus, Abbott's (ABT, Buy, $56 PT, Analyst: Dane Leone) IRIDICA platform likely poses the greatest competitive threat to T2. The IRIDICA platform uses a combination of polymerase chain reaction and electrospray ionization mass spectrometry (PCR/ESI–MS) to identify hundreds of targets. ABT's BAC BSI assay works directly off whole blood and can detect 750+ bacterial and *Candida* species, as well as 4 antibiotic resistance markers within ~6 hours. In 2014, data from ABT's RADICAL study, a multicenter observational study comparing results from direct blood specimen testing using PCR/ESI-MS to standard microbiology in critically-ill patients, showed sensitivity of 81%, specificity of 69%, a PPV of 24% and a NPV of 97%. Though we have no way to know for sure whether the T2Bacteria Panel will have rates of sensitivity and specificity as high as the T2Candida Panel, if it does, clinicians could see more utility in the T2Dx Instrument and T2Candida/T2Bacteria panels vs. ABT's IRIDICA.

While one could debate whether a test prior to positive blood culture will ever be adopted widely at an attractive price point (we discuss this in more detail below), we believe ABT's work helps validate T2's market opportunity to some extent and even if T2 struggles with commercialization initially, a large life sciences or tools company could see significant value in the company's technology.

Current and future collaborations could be meaningful.

In February 2015, T2 entered into a co-development partnership agreement with Canon U.S. Life Sciences, Inc. (CAJ, Not Rated) to develop a diagnostic test panel to rapidly detect Lyme disease. As part of this agreement, T2 received an upfront payment of $2M and the company may receive an additional $6.5M upon achieving certain development and regulatory milestones. The next payment that T2 is eligible for as part of this agreement is $1.5M related to the achievement of a specified technical requirement. T2 was able to retain exclusive worldwide commercialization rights of any products developed under this agreement and Canon is entitled to receive royalty payments on the sales of products developed under the agreement. With millions of Lyme disease tests run annually, this collaboration could result in meaningful revenue for T2 over time. Mgmt has noted that the company is open to additional collaborations, and as such agreements are signed, shares are likely to react favorably.

The Negatives

Our diligence suggests that the initial revenue ramp for T2Candida will be bleak.

Despite the positives discussed above, our surveys of infectious disease physicians and clinical microbiology lab directors/managers indicate that the commercialization of the T2Candida assay will be very challenging. Most notably, on a scale of 1 to 5 (1 being very unlikely to adopt T2Candida and 5

being very likely to adopt T2Candida), the infectious disease physician responses averaged a 3.2 (for likelihood of hospital/institution to adopt) and a 3.6 (for likelihood of the individual physician to adopt). Furthermore, on the same scale, the average among microbiology lab directors was a 2.1. Though our survey only covered ~45 U.S. hospitals, these figures do not bode well for T2Candida adoption, in our view.

Exhibit 3: Likelihood to Adopt TTOO's T2Candida Panel – Infectious Disease Physicians (n=35; top) and Clinical Microbiology Lab Directors/Managers (n=17; bottom)

	Average	1	2	3	4	5
On a scale of 1 to 5 (1=extremely unlikely to adopt; 5 = very likely to adopt) how likely is it that your hospital/institution will adopt T2 Biosystems' *Candida* Panel?	**3.2 out of 5**	6%	11%	46%	29%	9%
On a scale of 1 to 5 (1=extremely unlikely to adopt; 5 = very likely to adopt) how likely are you to adopt T2 Biosystems' *Candida* Panel?	**3.6 out of 5**	9%	3%	29%	37%	23%

1 = very unlikely to adopt	29.4%
2	35.3%
3	35.3%
4	0.0%
5 = very likely to adopt	0.0%
Average	**2.1 out of 5**

Source: BTIG Infectious Disease/Critical Care Physician Survey, May/June 2015; BTIG Microbiology Lab Director Survey, May/June 2015

If our survey results are accurate, consensus revenue will need to come down considerably over the next 1-2 years.

Despite signing only one contract in 1Q15, mgmt feels the company is on track to reaching its goal of 30 placements or so by year-end. While mgmt has communicated an expectation of 60% or more of these 30 placements occurring in 2H15, we are a tad skeptical of the company reaching this goal unless T2Candida pricing is revised downwards and/or the company begins placing free systems without volume minimums (both are possible).

Based on our surveys and our conversations with several other infectious disease physicians and clinical microbiology lab directors, we model 2015 revenue of $0.9M, 2016 revenue of $4.4M and 2017 revenue of $22.7M vs. consensus of $3.2M, $25.6M and $103.6M, respectively. While we do expect the T2Bacteria Panel to show strong clinical data and be approved in early 2017, 2018 is likely to be the full first year of its commercialization and we are skeptical that T2 will be able to meet consensus estimates with T2Candida alone in 2016 and with only a partial-year contribution of T2Bacteria in 2017.

Ultimately, while we see the clinical utility of T2Candida, we believe the panel is being priced too high in the absence of prospective outcomes data.

T2 surveyed over 100 decision markers involved with laboratory purchasing, including lab directors, hospital administrators, and infectious disease physicians to determine acceptable pricing for T2Candida and, based on this survey, which included rates of 90% sensitivity, 95% specificity (vs.T2's overall sensitivity of 91.1% and specificity of 99.4%) and a cost savings of $650 per

tested patient, the company believes that T2Candida would be adopted by nearly 50% of physicians at a selling price of $200 per test.

Additionally, 95% of laboratory directors and hospital administrators and 89% of infectious disease physicians, either "strongly agreed" or "agreed" that initiating appropriate antifungal therapy within 12 hours of a patient presenting with symptoms would reduce the mortality rate for candidemia patients from an average of 40% to ~10%, reduce hospitalization for each candidemia patient by an average of nine days (including two fewer days of stay in the ICU), and lead to a meaningful decrease in the utilization of antifungal therapy in a hospital due to cessation of therapy after a negative result. Finally, the surveyed physicians indicated that, on average, they would order T2Candida for approximately 75% of their patients considered at-risk for *Candida* infections.

Interestingly enough, our infectious disease survey yielded somewhat similar results in regards to potential clinical utility and the value of the information that T2Candida provides (see below), yet these same physicians do not necessarily plan to adopt the panel.

Exhibit 4: Questions on Clinical Utility of a Rapid Test for *Candida* Infection

	Mortality Only	Length of Hospital Stay Only	Length of ICU Stay Only	All of the Above	Mortality + Length of Hospital Stay Only	Mortality + Length of ICU Stay Only	Length of Hospital Stay + Length of ICU Stay Only	None of the above
Based on currently available data, do you believe that the **use of empiric antifungals within the first 12 hours** of suspicion/symptoms of infection can reduce any of the following in patients that you define as high-risk/at-risk for developing sepsis?	23%	9%	0%	9%	6%	0%	**49%**	6%
Do you believe that the use of **appropriate antifungals** (i.e. those recommended for a specifically identified species of fungus/fungi) **within the first 12 hours** of suspicion/symptoms of infection **could have a greater impact** on reducing any of the following in patients that you define as high-risk/at-risk for developing sepsis **vs. the use of empiric antifungals within the first 12 hours**?	29%	3%	9%	0%	3%	0%	**49%**	9%
Do you believe that the use of **appropriate antifungals** (i.e. those recommended for a specifically identified species of fungus/fungi) **within the first 12 hours** of suspicion/symptoms of infection **could have a greater impact** on reducing any of the following in patients that you define as high-risk/at-risk for developing sepsis **vs. the use of empiric antifungals within the first 72 hours?**	29%	9%	0%	0%	0%	0%	**54%**	9%

On a scale of 1 to 5 (1=useless; 5=extremely valuable) how valuable is the ability to know whether a patient that is considered high-risk/at-risk for developing sepsis is or is not infected with *Candida* and the species of *Candida* within 3-5 hours of a blood draw?

1 = useless	0.0%
2	2.9%
3	2.9%
4	37.1%
5 = extremely valuable	57.1%
Average	4.5 out of 5.0

Source: Source: BTIG Infectious Disease/Critical Care Physician Survey, May/June 2015; BTIG Microbiology Lab Director Survey, May/June 2015

Based on all of the literature we have reviewed, including the results of IMS Health's T2Candida economic study, which was published in *Future Microbiology* in April 2015, and an excel model we built (that does not factor in reduced rates of mortality or a reduction in empiric antifungal therapy post negative T2Candida results), we do believe that the adoption of T2Candida among patients deemed high-risk for developing sepsis could save a hospital money and do so even at a price point of ~$200 - $250/test. However given most physicians, lab directors, and hospital administrators do not view *Candida* as a significant issue within their institution, we believe the sticker shock of pricing T2Candida at ~$250/test is a non-starter, for several reasons.

1) **~90% of blood cultures come back negative for bacteria and fungi**. Though the rate of positive blood cultures is likely much higher among "high-risk" patients, with the prevalence of *Candida* ranging from ~2-10% even in this patient group, ~95%+ of T2Candida results are likely to come back negative. One lab director we spoke to commented that since his/her lab runs ~50k blood cultures annually (~5,000 among high-risk patients) and had 75 confirmed cases of *Candida* last year; the idea of spending over $10M dollars a year or even ~$1M a year (if T2Candida was only used in high-risk patients) to identify 75 *Candida* cases was unfathomable to him/her no matter what an excel model shows.

2) **T2Candida does not replace other testing methods**. Each identified clinically relevant pathogen in clinical microbiology is profiled for susceptibility and resistance. As a result, even in the cases where T2Candida detects and identifies *Candida* and its species, the lab still has to do a full work-up of the organism (from blood culture to susceptibility/resistance). While the T2Candida assay may save the hospital money outside the lab, it only adds costs within the lab.

3) **There are no clinical utility studies or outcome-studies showing which patients T2Candida should be used in**. Though various retrospective studies indicate that the administration of appropriate antifungals within hours of the onset of symptoms of infection vs. days can reduce hospital length of stay and improve mortality, there have been no prospective clinical utility studies showing if or how often physicians will change care based on the T2Candida test result and in what patient population this change provides the greatest benefit. Based on our conversations with physicians, if *Candida* is suspected in a critically ill patient, rather than ordering a T2Candida test for $250+, a physician would just prescribe a broad-spectrum empiric antifungal therapy like micafungin that covers all five of the common *Candida* species. Though the physicians admitted that in some cases *Candida* can be missed, they all commented that they would not have thought to order a T2Candida Panel for those patients anyway. Based on these comments, in the absence of clinical utility or outcome studies, we believe T2Candida needs to be priced at a level somewhat comparable to blood culture (~$50-$100/test) so that it can be used in all high-risk patients.

4) **Whether factual or not, most physicians simply do not view *Candida* as a significant concern.**

While we initially thought running a randomized, prospective clinical trial in a critically ill patient population would be unethical and impossible to enroll, with so many of the docs in our survey uninterested in adopting the T2Candida Panel, it seems such a study might be what is needed to drive widespread adoption.

Please see our published surveys for additional color on price sensitivity.

Although the mortality rate associated with sepsis caused by *Candida* is unacceptably high, it may be in part because the majority of physicians (at least the ones who responded to our survey) do not administer empiric antifungal therapy to begin

with, or adjust antifungal therapy post-identification of *Candida* species.

Among the infectious disease physicians we surveyed, ~70% administer empiric antibacterials to 80%+ of the patients defined as high-risk/at-risk for developing sepsis, with ~90% of these physicians commencing empiric antibacterial therapy within 12 hours of initial blood draw/culture (~22% prior to blood draw/culture, ~47% within one hour of initial blood draw/culture and ~20% within 12 hours of initial blood draw/culture). In contrast, when it comes to empiric antifungal therapy, ~75% administer empiric antifungals to under 20% of the patients defined as high-risk/at-risk for developing sepsis, with only ~60% of these physicians commencing the use of empiric antifungals within 12 hours of initial blood draw/culture (~15% prior to blood draw/culture, ~24% within one hour of initial blood draw/culture and ~21% within 12 hours of initial blood draw/culture). Furthermore, despite the majority of the physicians stating that it takes 25+ and 33+ hours to confirm the presence and species of *Candida*, respectively, in high-risk/at-risk patients, only ~34% of our survey respondents adjust a patient's empiric antifungal therapy in the majority of their patients post the identification and/or species of *Candida* present. These results indicate that the increased use of empiric antifungal therapy (even without T2Candida) might also provide a significant reduction in *Candida* mortality and save hospitals money.

Competition

While T2 seems to have first mover advantage in the U.S., there are several companies working on competing technologies. Abbott's IRIDICA (discussed above), which is currently CE marked, is likely T2's closest competitor and if ABT is able to improve the platform's sensitivity and specificity rates to levels comparable to T2 (we are unsure if this is possible given the system's currently reported levels of detection), IRIDICA's broad menu and ABT's vast sales and marketing organization may make it difficult for T2 to compete. Additionally, if companies such as Accelerate Diagnostics (AXDX, Neutral) are successful in bringing platforms to market that can not only identify a pathogen, but also provide information on susceptibility/resistance within 5 hours post-positive culture (as rapidly as ~14-16 hours post blood draw), the value of a detection/identification technology within ~5 hours of blood draw could be somewhat muted.

Even hospitals interested in adopted T2Candida may wait for the T2Bacteria Panel to adopt.

In our survey, we asked both the infectious disease physicians and clinical microbiology lab directors to rank potential reasons a physician/lab would not adopt T2Candida, with 5 being a common reason and 1 being an unlikely reason. In both cases waiting for the bacteria panel to be approved ranked high among common reasons T2Candida would not be adopted. With T2Bacteria likely to reach the U.S. market by early 2017, physicians and labs might decide it makes the most sense to wait to adopt T2Candida in conjunction with T2Bacteria.

Exhibit 5: Reasons T2Candida Is Unlikely to be Adopted (infectious disease physicians – top; clinical microbiology lab directors – bottom)

	Average
Pricing of $200-250/test	3.54
Waiting for the bacteria panel to be approved	3.09
The quantity/quality of available data on the test's sensitivity and specificity	3.03
Skepticism around T2's panel having an impact on reducing mortality and/or hospital/ICU length of stay	3.00
Candida not being a concern due to its low prevalence	2.94
Skepticism around T2's panel impacting the use of antibacterials or antifungals	2.86
The adoption of other emerging technologies is more important at this time	2.77

5 = very likely to be a common reason why a lab would not adopt T2Candida	Average
Pricing of $200-250/test	4.4
The replacement of other instruments/assays being more important/timely over the next 12-18 months	3.9
Candida not being a concern due to its low prevalence	3.8
Negotiation of a minimum number of samples/year contract	3.5
Waiting for the bacteria panel to be approved	3.4
Skepticism around T2's panel impacting the use of antibacterials or antifungals	2.9
Skepticism around T2's panel having an impact on reducing mortality and/or hospital/ICU length of stay	2.5
Critical care/infectious disease physicians not being interested in adopting the test	2.4
The quantity/quality of available data on the test's sensitivity and specificity	1.9
Purchasing from a small company	1.6
1 = very unlikely to be a common reason why a lab would not adopt T2Candida	

Source: Source: BTIG Infectious Disease/Critical Care Physician Survey, May/June 2015; BTIG Microbiology Lab Director Survey, May/June 2015

Microbiology labs can be slow to adopt even the most innovative of technologies.

Despite significant advances in clinical microbiology over the past decade, various manual, labor-intensive, and slow techniques have maintained a large portion of share within hospital labs. This phenomenon has occurred for multiple reasons, including cost, complexity, limited throughput, and concerns about reported rates of accuracy. During our channel checks, we even came across clinicians whose labs had adopted automated platforms for identification and AST(antibiotic susceptibility testing), but then eventually reverted back to archaic manual methods. Since microbiology labs are generally viewed as cost centers, the incremental costs associated with adopting new technologies must be offset by savings within other parts of the hospital. All told, no matter how innovative, consistent, reliable, or accurate a new technology might be, an attractive cost-benefit model is essential to both widespread adoption and continual use in our view.

Additional capital will be needed.

T2 ended 1Q15 with ~$65M of cash and cash equivalents. We believe the company will need additional capital over the next few years before becoming profitable. If capital is not available or is expensive to obtain, shares may suffer.

Essentially a single product company.

Though T2 plans to launch additional tests over the next few years, today T2 is essentially a single product company. With all of 2015 and 2016 revenue

expected to come from sales of the T2Dx instrument and the T2Candida Panel, any recalls, manufacturing issues, or regulatory issues could have a large impact on the company's results.

What Could Make Us More Positive?

While much of the research we did left us conflicted with what to do with the stock given our bullish view of the technology and its potential clinical utility, particularly with bacterial infections, our near-term major concerns about T2Candida commercialization coupled with aggressive consensus estimates that we think are likely to be revised downward multiple times lead us to a Neutral rating. However, we note that there are multiple happenings that could change our view. These include:

1) **A change in T2Candida pricing**. T2 could lower T2Candida pricing to a level where more infectious disease physicians and microbiology lab directors see value in adopting the test for a meaningful subset of their high-risk patients, even in the absence of clinical utility studies. Our survey results suggest that this price may be closer to ~$150/test.
2) **T2Bacteria data**. Data from the T2Bacteria clinical trial could/should look stellar and give us incremental confidence that hospitals will adopt the T2Dx platform once a test beyond T2Candida is available.
3) **The commencement of a clinical utility/outcomes study that has the potential to change current standard of care**. We believe T2 should run a clinical utility/outcomes trial for T2Candida and/or T2Bacteria. If such a trial were to show lower mortality rates, reduced hospital and ICU length of stays and cost savings (as we expect they would based on published literature), we believe T2Candida/T2Bacteria would move to standard of care among patients who are considered high-risk of developing sepsis. Though such a trial would be expensive and could potentially take years to enroll, based on all of our diligence we are confident that the results would look favorable and help drive the adoption of T2Candida/T2Bacteria.
4) **Quarterly results showing that our surveys were wrong**. Quarterly results showing large numbers of system placements in 2015 *and* meaningful recurring revenue in 2016 (illustrating that placed systems are actively being used) would force us to reconsider our view. Such results would indicate that perhaps our surveys were skewed to a minority of non-believers.
5) **A valuation/numbers reset**. Despite our skepticism around near-term T2Candida adoption and our view that consensus numbers need to come down considerably, we believe T2's platform addresses a very important unmet need within clinical microbiology diagnostics today. At the right valuation, we believe TTOO's risk/reward would skew to the upside, particularly for investors with multi-year time horizons.

Valuation

We believe a DCF is the most appropriate way to value TTOO at this time. We assume T2Bacteria obtains FDA approval in early 2017, but use a 20% discount rate to reflect both development and regulatory risk. We do not include revenue for T2Stat or T2Lyme in our model at this time, leaving both pipeline products as potential sources of upside.

Our T2 Biosystems rating is Neutral. Our DCF suggests that TTOO's current fair value is ~$330M, which is within 15% of current levels. BTIG does not provide price targets on Neutral-rated stocks.

Risks include: commercial execution, competition, clinical data, M&A, need for additional capital, regulatory, and IP.

Exhibit 6: TTOO DCF

TTOO DCF Model																						
$ millions	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E
Product Revenue	**$4.4**	**$22.7**	**$80.9**	**$137.5**	**$206.3**	**$288.8**	**$375.5**	**$450.6**	**$495.6**	**$535.3**	**$562.1**	**$578.9**	**$596.3**	**$614.2**	**$632.6**	**$651.6**	**$671.1**	**$691.3**	**$712.0**	**$733.4**	**$755.4**	**$778.0**
y/y growth		*419.3%*	*255.9%*	*70.0%*	*50.0%*	*40.0%*	*30.0%*	*20.0%*	*10.0%*	*8.0%*	*5.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*	*3.0%*
Gross Profit	1.4	12.2	49.1	85.3	128.9	182.0	238.4	288.4	319.7	347.9	371.0	387.9	405.5	423.8	442.8	456.1	469.8	483.9	498.4	513.3	528.7	544.6
Margin	*32.6%*	*53.6%*	*60.7%*	*62.0%*	*62.5%*	*63.0%*	*63.5%*	*64.0%*	*64.5%*	*65.0%*	*66.0%*	*67.0%*	*68.0%*	*69.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*	*70.0%*
Operating Expenses	56.6	72.8	95.0	104.5	115.5	124.2	135.2	144.2	151.2	155.2	157.4	156.3	155.0	153.5	151.8	156.4	161.1	165.9	170.9	176.0	181.3	186.7
% of revenues		*320.2%*	*117.4%*	*76.0%*	*56.0%*	*43.0%*	*36.0%*	*32.0%*	*30.5%*	*29.0%*	*28.0%*	*27.0%*	*26.0%*	*25.0%*	*24.0%*	*24.0%*	*24.0%*	*24.0%*	*24.0%*	*24.0%*	*24.0%*	*24.0%*
Operating Profit	-55.2	-60.6	-45.9	-19.3	13.4	57.8	103.3	144.2	168.5	192.7	213.6	231.6	250.4	270.2	291.0	299.7	308.7	318.0	327.5	337.3	347.5	357.9
Margin		*-266.6%*	*-56.8%*	*-14.0%*	*6.5%*	*20.0%*	*27.5%*	*32.0%*	*34.0%*	*36.0%*	*38.0%*	*40.0%*	*42.0%*	*44.0%*	*46.0%*	*46.0%*	*46.0%*	*46.0%*	*46.0%*	*46.0%*	*46.0%*	*46.0%*
NOLs	-191.8	-260.4	-314.3	-260.4	-247.0	-189.2	-86.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Taxes	25.0%	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*	*36.0*	*42.1*	*48.2*	*53.4*	*57.9*	*62.6*	*67.6*	*72.7*	*74.9*	*77.2*	*79.5*	*81.9*	*84.3*	*86.9*	*89.5*
NOPAT		*-61*	*-46*	*-19*	*13*	*58*	*103*	*108*	*126*	*145*	*160*	*174*	*188*	*203*	*218*	*225*	*232*	*238*	*246*	*253*	*261*	*268*
Period		0.00	0.25	1.25	2.25	3.25	4.25	5.25	6.25	7.25	8.25	9.25	10.25	11.25	12.25	13.25	14.25	15.25	16.25	17.25	18.25	19.25
Factor		1.00	0.96	0.80	0.66	0.55	0.46	0.38	0.32	0.27	0.22	0.19	0.15	0.13	0.11	0.09	0.07	0.06	0.05	0.04	0.04	0.03
Discount Rate	20%																					
PV of NOPAT	328																					
Fully Diluted Shares	23.0																					
Est. Value (M)	**$328**																					

Note: BTIG does not provide price targets on neutral-rated stocks.

Source: BTIG Research estimates

Potential Upcoming Trading Events

Quarterly Reports: We believe the number of contracts signed/T2Dx instruments placed is the most important metric for shares over the next several quarters. Additionally, investors will be interested in pipeline updates, including the commencement of a FDA pivotal trial for T2Bacteria (expected by the end of 2015) and the T2HemoStat instrument and T2Stat assay (expected in 2016). Beyond 2015, we believe revenue will start to matter more as investors will want to see that placed systems are being utilized.

Timing Unknown – Additional Data Presentations for T2Candida: Additional data publications showing the clinical utility of T2Candida could boost shares. We expect hospitals that adopt T2Candida to publish data on their experiences with the panel. Should such publications show a meaningful reduction in mortality/length of stay, we would expect shares to react favorably.

2015 - 2017 – Commencement of T2Bacteria Trial (2015), Data (est. 2016), and a Potential FDA Decision (est. 2017): Using timelines similar to what we saw with T2Candida (FDA approval was obtained ~13 months post the commencement of the pivotal FDA trial), if the T2Bacteria trial begins by the end of 2015, we would expect the product could be launched in the U.S. by early 2017. If the company is able to start the T2Bacteria trial in the next few months, we could even see a FDA approval and launch in late 2016.

2016 - 2017 – Data on T2Lyme: Though T2Lyme is still early in development, updates on the assay's development and favorable data could serve as positive catalysts for shares.

Timing Unknown – Announcement of Additional Collaborations: Mgmt has communicated that the company would consider additional collaborations that make sense. The announcement of such collaborations, particularly those that offer non-dilutive financing could lead shares higher.

Market Opportunity

Healthcare-Associated Infections (HAIs) & Sepsis: T2Candida & T2Bacteria

Healthcare-associated infections (HAIs) are infections developed by patients while receiving healthcare treatment for other conditions; they are considered a major, yet often preventable, threat to patient safety. HAIs can be caused by a variety of pathogens, including bacteria, fungi, and viruses and occur across all healthcare facilities, including hospitals, outpatient surgery centers, dialysis centers, long-term care facilities (nursing homes, rehabilitation centers) and community clinics.

Per the World Health Organization (WHO), of every 100 hospitalized patients, ~7 in developed and ~10 in developing countries will acquire at least one healthcare-associated infection. In high-income countries, ~30% of patients in intensive care units (ICU) are affected by at least one healthcare-associated infection and in low- and middle-income countries the frequency of ICU-acquired infection is at least 2-3x higher than this ~30%.

The European Centre for Disease Prevention and Control has reported an average prevalence of HAIs of 7.1% in European countries, with 4,131,000 patients affected by approximately 4,544,100 episodes of healthcare-associated infections every year in Europe. Per the WHO and according to a recent European multicenter study, the percentage of infected patients in the ICU can be as high as 51%.

According to data collected from a large sample of U.S. acute care hospitals, and reported by the CDC, on any given day ~1 in 25 hospital patients has at least one healthcare-associated infection. In 2011, there were an estimated 722,000 HAIs within U.S. acute care hospitals and ~75,000 hospital patients with HAIs died during their hospitalization, despite over 50% of these HAIs occurring outside the ICU.

Exhibit 7: Estimates of Healthcare-Associated Infections Occurring in Acute Care Hospitals in the United States, 2011

Major Site of Infection	Estimated No.
Pneumonia	157,500
Gastrointestinal Illness	123,100
Urinary Tract Infections	93,300
Primary Bloodstream Infections	71,900
Surgical site infections from any inpatient surgery	157,500
Other types of infections	118,500
Estimated total number of infections in hospitals	**721,800**

Source: CDC

The CDC publishes a National and State Healthcare-Associated Infections Progress Report each year that provides information on HAIs most commonly reported to the CDC via the National Healthcare Safety Network (NHSN). This report also includes information on national and statewide progress in

preventing 1) central line-associated bloodstream infections (CLABSI), 2) catheter-associated urinary tract infections (CAUTI), 3) select surgical site infections (SSI), 4) hospital-onset *Clostridium difficile* infections (*C. difficile*), and 5) hospital-onset methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia (bloodstream infections). The most recent published report we found was from 2013 (published January 2015); this report found that on a national level there was a:

> 46 percent decrease in CLABSI between 2008 and 2013,
>
> 19 percent decrease in SSIs related to the 10 select procedures tracked in the report between 2008 and 2013,
>
> 6 percent increase in CAUTI between 2009 and 2013 (although initial data from 2014 seem to indicate that these infections have started to decrease),
>
> 8 percent decrease in hospital-onset MRSA bacteremia between 2011 and 2013, and a
>
> 10 percent decrease in hospital-onset *C. difficile* infections between 2011 and 2013.

While these statistics indicate that some progress is being made, the nation did not reach the 2013 goals that had been set in 2009 by the U.S. Department of Health and Human Services (HHS) and as such it was concluded by the CDC that more actions are needed to improve patient safety and eliminate infections that commonly threaten hospital patients.

Despite the significant number of deaths described above, an effective drug exists for nearly every HAI today and while many of the patients who develop HAIs are very sick and end up dying from another comorbidity, antibiotic resistance and lab delays are considered two major factors that lead to HAIs having such a high prevalence and mortality rate.

First, on antibiotic resistance. Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a direct result of these infections, per the CDC. The use of antibiotics is the single most important factor that is leading to antibiotic resistance in our world today. However, since there is substantial data to support that a delay in antibiotic administration post the onset of infection significantly increases the mortality rate of critically ill patients, most physicians begin empiric broad-spectrum antibiotic therapy prior to the identification of the organism and/or before knowing which drugs the organism is susceptible or resistant to. While this is less than ideal and most certainly leads to higher rates of antibiotic resistance, clinicians essentially have no choice, as it can often take days before the microbiology lab is able to report specific identification and susceptibility/resistance information. Also according to the CDC, antibiotics are among the most commonly prescribed drugs used in human medicine; however, up to 50% of the time antibiotics are not optimally prescribed, prescribed when not needed, and/or are incorrectly dosed (based on both quantity and duration of therapy).

Besides the common ways to fight antibiotic resistance (preventing infections, preventing the spread of infections, tracking data, putting antibiotic stewardship programs in place, developing new drugs, etc.), the development of new rapid diagnostic tests that enable the identification and

susceptibility/resistance profiling of organisms in question should help maximize the efficacy of antibiotics and decrease the use of inappropriate antibiotics, both of which should help combat the growth of resistant organisms and reduce the rate of mortality from HAIs.

The rate of mortality linked to HAIs given modern day medicine is considered unacceptable by experts and furthermore, HAIs are very expensive to manage. A study published in 2010 in the *Archives of Internal Medicine* analyzed ~69 million discharge records from hospitals in 40 states and identified two common conditions caused by HAIs: pneumonia and sepsis. It was estimated that these two conditions alone took ~48,000 U.S. lives and increased healthcare costs by ~$8.1B in 2006. Since TTOO is initially focused on how the T2Candida and T2Bacteria assays can reduce sepsis-related mortality and costs, we will now shift to the discussion of sepsis.

Sepsis is a potentially life-threatening complication of an infection and is one of the leading causes of death in the United States. Given the challenges associated with predicting, diagnosing, and treating sepsis, in addition to its high mortality rate (~20-60%), the costs associated with sepsis are astronomical.

For those unfamiliar with how sepsis is caused we would use getting a minor cut as a simple example. When a person suffers a minor cut, the area around the cut typically swells and becomes hot and red. This is due to the body's immune response. In order to fight/prevent an infection and to stop the cut's bleeding, white blood cells and platelets must get to the area of injury. The body's ability to enable this is called inflammation and during inflammation blood vessels swell (to allow for more blood to flow) and become more leaky (to allow for WBCs and clotting factors to escape into the tissues where they are needed). Sepsis occurs when the body responds to an infection, yet the inflammation process described above is essentially on overdrive.

Since this response occurs beyond just in the area of injury like with what happens after a minor cut, the impaired blood flow and leaky vessels can quickly lead to organ damage and failure as the body's organs are deprived of important oxygen and nutrients that must be obtained from blood. Immune responses vary widely from patient to patient and as a result the severity of sepsis and its speed of progression are impacted by numerous factors, including the presence of coexisting illnesses, the numbers and virulence of the infecting organism, and even genetic characteristics. For some patients, it can take a day or two for clinicians to notice an emerging case of sepsis, whereas in other cases, sepsis can progress very rapidly and became fatal within just a few hours.

Various types of infections (skin, lungs, urinary tract, abdomen) and pathogens (bacteria, fungi, viruses) can cause sepsis. In the majority of cases, sepsis stems from known infections such as pneumonia, urinary tract infections, skin infections like cellulitis and infections in the abdomen (think appendicitis). Bacteria is the most common causative pathogen and a 2013 study published in the *New England Journal of Medicine* reported that in severe sepsis cases, *Staphylococcus aureus* and *Streptococcus pneumoniae* are the most common gram-positive isolates, and *Escherichia coli*, *klebsiella* species, and *Pseudomonas aeruginosa* predominate among gram-negative isolates.

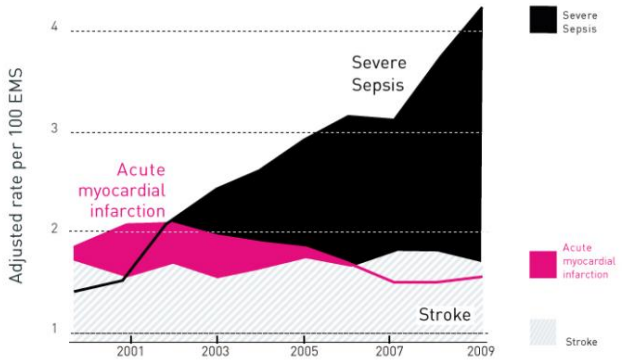
Though anyone can become septic, the risk is generally higher in the following patient populations.

1) People with weakened immune systems;
2) Infants and children;
3) The elderly;
4) People with chronic illnesses, such as AIDS, cancer, diabetes, etc.; and
5) People suffering from a severe burn or physical trauma.

Age, sex, race, and/or ethnic group also play a role with higher rates of prevalence in infants and the elderly vs. other age groups, men vs. women, and African Americans vs. Caucasians.

Per 2008 data published by the CDC's National Center for Health Statistics, the number of sepsis/septicemia cases in the U.S. increased from 621,000 in 2000 to 1,141,000 in 2008 (+84%). During 2000 and 2007 the number of deaths from sepsis in the U.S. also increased from 154,159 in 2000 to 207,427 in 2007 (+35%). Based on these figures, sepsis causes more deaths in the U.S. than prostate cancer, breast cancer, and AIDs combined. According to a 2013 study published in the *New England Journal of Medicine*, severe sepsis is reported in 2% of patients admitted to the hospital in the U.S. and of these patients, ~50% are treated in the ICU, representing ~10% of all ICU admissions. In addition, the number of hospital admissions due to sepsis following healthcare-associated and community-acquired infections has risen nearly three-fold in the last decade, whereas hospitalizations for myocardial infarction and stroke for example have remained relatively stable over the same period of time.

Exhibit 8: Hospital Admissions for Sepsis vs. Acute Myocardial Infarction vs. Stroke



Source: Global Sepsis Alliance, Center for Sepsis Control & Care, 2015 Fact Sheet

Turning to sepsis as a global consideration, a 2014 assessment including over 10,000 ICU patients across Europe, Asia, the Americas, Oceania, the Middle East, and Africa and published in *The Lancet Respiratory Medicine* showed that that ICU mortality rates were 16.2% across the whole population vs. 25.8% in patients with sepsis. Hospital mortality rates were 2.4% across the whole population vs. 35.3% among patients with sepsis. Additional details related to this assessment are included in the table below.

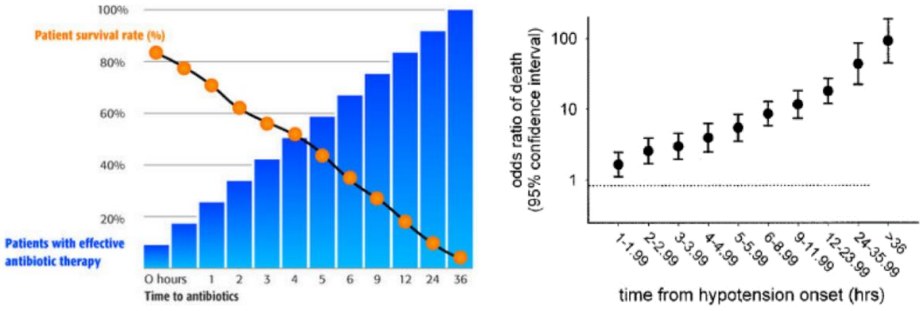
Exhibit 9: Results from International Audit of ~10,000 ICU Patients Worldwide

	Number of centres	Number of patients (%)	Mean age, years (SD)	Mean SAPS II score (SD)	Mean APACHE II score (SD)	Number of cases of sepsis (%)	Mortality rate, % (95% CI)		Median length of stay, days (IQR)		Number of patients receiving mechanical ventilation (%)	Number of patients receiving RRT (%)
							ICU	In-hospital	ICU	In-hospital		
Total	730	10069	60 (18)	40·2 (18·2)	17·9 (9·4)	2973 (29·5%)	16·2 (15·5-16·9)	22·4 (21·6-23·2)	3 (2-6)	10 (5-20)	5407 (53·7%)	1229 (12·2%)
Region												
Western Europe	317	4335 (43·1%)	63 (17)	41·7 (18·1)	18·8 (9·2)	1357 (31·3%)	15·5 (14·4-16·6)	22·6 (21·3-23·9)	3 (1-6)	11 (6-22)	2514 (58·0%)	553 (12·8%)
Eastern Europe	87	1110 (11·0%)	60 (17)	41·2 (18·2)	18·0 (9·4)	336 (30·3%)	21·9 (19·5-24·3)	27·2 (24·5-29·9)	3 (2-7)	10 (6-18)	651 (58·6%)	113 (10·2%)
South America	109	993 (9·9%)	59 (20)	40·8 (18·8)	17·1 (9·4)	303 (30·5%)	21·7 (19·0-24·4)	29·4 (26·2-32·6)	4 (2-7)	9 (5-20)	509 (51·3%)	127 (12·8%)
North America	23	730 (7·2%)	59 (18)	35·9 (16·5)	17·0 (8·4)	147 (20·1%)	9·3 (7·2-11·4)	13·1 (10·6-15·6)	2 (1-4)	6 (3-14)	267 (36·6%)	60 (8·2%)
East and southeast Asia	91	946 (9·4%)	60 (18)	43·2 (17·2)	19·8 (9·6)	372 (39·3%)	16·6 (14·2-19·0)	23·7 (20·9-26·5)	4 (2-7)	11 (5-25)	571 (60·4%)	150 (15·9%)
South Asia	36	982 (9·8%)	55 (17)	31·3 (16·8)	13·2 (8·4)	134 (13·6%)	10·9 (8·9-12·9)	14·4 (12·0-16·8)	2 (1-4)	6 (2-10)	317 (32·3%)	73 (7·4%)
Oceania	20	439 (4·4%)	58 (18)	41·2 (14·7)	18·5 (7·7)	135 (30·8%)	10·3 (7·5-13·1)	13·8 (10·6-17·0)	2 (1-5)	8 (4-17)	256 (58·3%)	45 (10·3%)
Middle East	36	393 (3·9%)	55 (20)	42·1 (20·8)	19·7 (11·2)	151 (38·4%)	26·2 (21·8-30·6)	34·1 (29·3-38·9)	4 (2-9)	10 (5-23)	252 (64·1%)	76 (19·3%)
Africa	11	141 (1·4%)	48 (19)	36·1 (17·4)	15·3 (9·2)	38 (27·0%)	16·9 (10·5-23·3)	20·7 (13·3-28·1)	2 (1-5)	8 (3-16)	70 (49·6%)	32 (22·7%)
GNI												
Low and lower-middle income	62	1209 (12·0%)	55 (17)	33·4 (17·5)	14·3 (8·9)	198 (16·4%)	14·1 (13·0-15·1)	18·2 (17·0-19·4)	2 (1-4)	6 (2-10)	432 (35·7%)	87 (7·2%)
Upper-middle income	237	2504 (24·9%)	58 (19)	40·7 (18·0)	17·7 (9·4)	790 (31·5%)	21·4 (20·3-22·2)	27·5 (26·6-28·5)	4 (2-7)	10 (5-19)	1377 (55·0%)	349 (13·9%)
High income	431	6356 (63·1%)	62 (18)	41·2 (18·1)	18·7 (9·3)	1985 (31·2%)	14·6 (13·8-15·5)	21·2 (20·7-21·8)	3 (1-6)	11 (5-21)	3598 (56·6%)	793 (12·5%)

Source: Assessment of the worldwide burden of critical illness: the intensive care over nations (ICON) audit; published in The Lancet Respiratory Medicine, 2014

Per company estimates, over 1.6M individuals are diagnosed with sepsis each year, ~1.35M of whom would have been considered "at high-risk for infection" prior to contracting sepsis due to having a suppressed immune system or because of their stay within a critical care unit. Based on our diligence, it seems the majority of these "high-risk" patients are rapidly treated with broad-spectrum empiric antibiotics upon the presentation of initial symptoms. This makes sense to us given there is ample data to support the belief that for every hour antibiotic therapy is delayed, the rate of mortality due to sepsis rises. The below charts illustrate this point quite effectively, though we note that exact rates of mortality at various time periods vary from study to study due to several factors, including, but not limited to the following: type, quantity and susceptibility/resistance profile of the infecting pathogen, patient co-morbidities, and type of antibiotic therapy administered.

Exhibit 10: Survival vs. Time to Effective Antibiotics (left) and Mortality Risk (expressed as adjusted odds ratio of death) with Increasing Delays in Initiation of Effective Antimicrobial Therapy (right)



Sources: bioMerieux Presentation at World Sepsis Day 2009 (left); Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock" Critical Care Medicine, 2006 (right)

Physicians typically diagnose sepsis or confirm the suspicion of sepsis through a patient's clinical presentation (temperature, heart rate, breathing rate, etc.) and the use of laboratory tests and/or imaging modalities. A patient's blood is typically tested for clotting issues, abnormal liver or kidney function, impaired oxygen availability, electrolyte imbalances, and/or the presence of an abnormal number of white blood cells. Additionally, a series of blood cultures (a laboratory test that detects the presence of bacteria and/or other microorganisms in a patient's bloodstream) are ordered. If the blood culture (BC) comes back positive, additional tests will be conducted to identify the species of microorganism(s) detected and determine which drugs should be used to kill the pathogen(s).

Despite advances in newer molecular technologies, blood cultures are still considered the 'gold standard' for the detection of microbial pathogens related to bacteraemia and sepsis due to their low cost. However, blood cultures have several limitations including: 1) their mechanism of action requires the organism to grow and thus it takes time (anywhere from ~8 hours to several days) for a positive result, 2) sensitivity is limited (particularly with fastidious pathogens), and 3) the detection of some bacteraemias is not feasible via blood culture if the blood is taken post the administration of antimicrobial therapy. According to an article published in the *NEJM* in 2013, in patients with severe sepsis, blood cultures are typically positive in only one third of cases. Based on all of the above, we believe there is a significant need for a technology, such as T2's T2MR, to be used in conjunction with blood culture.

Most patients with sepsis are treated in intensive care units (ICUs) and in addition to using antibiotics to treat the infection, clinicians must work to sustain the patient's vital organs and prevent drops in blood pressure. Oxygen and IV fluids are commonly administered and in severe cases a patient may be placed on a ventilator and/or a dialysis machine for prolonged periods of time. According to data published by the U.S. Department of Health and Human Services in 2011, the cost of sepsis in the U.S. amounts to over $20B each year, representing ~5% of the total aggregate costs associated with domestic hospital stays and making sepsis the most expensive condition treated.

Exhibit 11: Top 10 Most Expensive Conditions Treated in U.S. Hospitals, 2011

Rank	CCS principal diagnosis category and name	Aggregate hospital costs, U.S. $, in millions	National costs, %	Number of hospital discharges, in thousands
1	Septicemia (except in labor)	20,298	5.2	1,094
2	Osteoarthritis	14,810	3.8	964
3	Complication of device, implant or graft	12,881	3.3	699
4	Liveborn	12,390	3.2	3,818
5	Acute myocardial infarction	11,504	3.0	612
6	Spondylosis, intervertebral disc disorders, other back problems	11,218	2.9	667
7	Pneumonia (except that caused by tuberculosis and sexually transmitted diseases)	10,570	2.7	1,114
8	Congestive heart failure, nonhypertensive	10,535	2.7	970
9	Coronary atherosclerosis	10,400	2.7	605
10	Respiratory failure, insufficiency, arrest (adult)	8,749	2.3	404

Source: Agency for Healthcare Research and Quality (AHRQ), Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project (HCUP), Nationwide Inpatient Sample (NIS), 2011

Sepsis Guidelines

In 2012, "Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock" were published. This publication was an update to the "Surviving Sepsis Campaign Guidelines for Management of Severe Sepsis and Septic Shock," last published in 2008. To formulate these guidelines, a consensus committee of 68 international experts representing 30 international organizations was convened. Most of the recommendations are appropriate for severe sepsis patients in the ICU and non-ICU setting, with the committee even stating that the greatest outcome improvement can be made through education and process change for those caring for severe sepsis patients in the non-ICU setting and across the spectrum of acute care.

Exhibit 12: Screening for Sepsis and Performance Improvement, Recommendations on Diagnosis and Antimicrobial Therapy

C. Diagnosis

1. Cultures as clinically appropriate before antimicrobial therapy if no significant delay (> 45 mins) in the start of antimicrobial(s) (grade 1C). At least 2 sets of blood cultures (both aerobic and anaerobic bottles) be obtained before antimicrobial therapy with at least 1 drawn percutaneously and 1 drawn through each vascular access device, unless the device was recently (<48 hrs) inserted (grade 1C).
2. Use of the 1,3 beta-D-glucan assay (grade 2B), mannan and anti-mannan antibody assays (2C), if available and invasive candidiasis is in differential diagnosis of cause of infection.
3. Imaging studies performed promptly to confirm a potential source of infection (UG).

D. Antimicrobial Therapy

1. Administration of effective intravenous antimicrobials within the first hour of recognition of septic shock (grade 1B) and severe sepsis without septic shock (grade 1C) as the goal of therapy.

2a. Initial empiric anti-infective therapy of one or more drugs that have activity against all likely pathogens (bacterial and/or fungal or viral) and that penetrate in adequate concentrations into tissues presumed to be the source of sepsis (grade 1B).

2b. Antimicrobial regimen should be reassessed daily for potential deescalation (grade 1B).

3. Use of low procalcitonin levels or similar biomarkers to assist the clinician in the discontinuation of empiric antibiotics in patients who initially appeared septic, but have no subsequent evidence of infection (grade 2C).

4a. Combination empirical therapy for neutropenic patients with severe sepsis (grade 2B) and for patients with difficult-to-treat, multidrug-resistant bacterial pathogens such as *Acinetobacter* and *Pseudomonas* spp. (grade 2B). For patients with severe infections associated with respiratory failure and septic shock, combination therapy with an extended spectrum beta-lactam and either an aminoglycoside or a fluoroquinolone is for *P. aeruginosa* bacteremia (grade 2B). A combination of beta-lactam and macrolide for patients with septic shock from bacteremic *Streptococcus pneumoniae* infections (grade 2B).

4b. Empiric combination therapy should not be administered for more than 3–5 days. De-escalation to the most appropriate single therapy should be performed as soon as the susceptibility profile is known (grade 2B).

5. Duration of therapy typically 7–10 days; longer courses may be appropriate in patients who have a slow clinical response, undrainable foci of infection, bacteremia with *S. aureus;* some fungal and viral infections or immunologic deficiencies, including neutropenia (grade 2C).

6. Antiviral therapy initiated as early as possible in patients with severe sepsis or septic shock of viral origin (grade 2C).

7. Antimicrobial agents should not be used in patients with severe inflammatory states determined to be of noninfectious cause (UG).

Grading Scale: Assessment of quality of evidence: high (grade A, RCTs), moderate (grade B, downgraded RCTs or upgraded observational studies), low (grade C, well-done observational studies with control RCTs), or very low (grade D, downgraded controlled studies or expert opinion based on evidence). Assessment of recommendation: strong (grade 1) or weak (grade 2).

Source: Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock, 2012

Per IDSA guidelines, it is recommended that blood cultures be taken before antimicrobial therapy is initiated, although such sampling should not delay the timely administration of antimicrobial agents in patients with severe sepsis. These cultures are important to confirm infection and the responsible pathogens, as well as to allow the de-escalation of antimicrobial therapy upon receipt of the pathogen's susceptibility profile.

Regarding treatment, the administration of effective intravenous antimicrobials within the first hour of recognition of septic shock (grade 1B) and severe sepsis without septic shock (grade 1C) should be the goal of therapy (given significant data supports the premise that the administration of antibiotics as close to the onset of sepsis symptoms can reduce mortality). Surprisingly, despite the strong recommendation for administering antibiotics within 1 hr of the diagnosis of severe sepsis and septic shock, the committee noted that this practice is not yet considered the standard of care as verified by published practice data.

Today, there are many factors that impact the choice of empirical antimicrobial therapy, including a patient's history, including drug intolerances, recent receipt of antibiotics (previous 3 months), underlying disease, clinical syndrome, and susceptibility patterns of pathogens in the community and hospital. The most common pathogens that cause septic shock in hospitalized patients are Gram-positive bacteria, followed by Gram-negative bacteria and then mixed bacterial microorganisms. Clinicians are advised to generally avoid recently used anti-infective agents and when selecting which empirical therapy to use they should be cognizant of the virulence trends and the growing prevalence of antibiotic resistance. Examples of this include: *oxacillin (methicillin)-resistant Staphylococcus aureus*, and resistance to broad-spectrum beta-lactams and carbapenem among Gram-negative bacilli in some communities and healthcare settings.

The committee noted that there is ample evidence that supports the view that failure to initiate appropriate therapy results in increased morbidity and mortality in patients with severe sepsis or septic shock and as such these patients should receive broad-spectrum therapy until the causative organism and its antimicrobial susceptibilities are determined. Then, once the causative pathogen has been identified, de-escalation is recommended by selecting the most appropriate antimicrobial agent that covers the pathogen and is safe and cost-effective. We note that the IDSA committee did suggest that the continued use of specific combinations of antimicrobials might be indicated even after susceptibility testing is available on occasion. Finally, the ability to narrow the spectrum and reduce the duration of antimicrobial therapy is viewed as essential to reduce the likelihood that the patient will develop a superinfection with other pathogenic or resistant organisms.

Per guidelines, clinicians should consider whether *Candida* is a likely pathogen when choosing initial therapy and use empirical antifungal therapy when warranted. The choice of empiric antifungal therapy should be based on the local pattern of the most prevalent *Candida* species and any recent exposure to antifungal drugs with current guidelines recommending either fluconazole or an echinocandin. Other risk factors for candidemia, such as immunosuppressed or neutropenic state, prior intense antibiotic therapy, or

colonization in multiple sites, should also be considered when choosing initial empiric therapy.

Exhibit 13: Excerpt from Clinical Practice Guidelines for the Management of Candidiasis: 2009 Update by the Infectious Diseases Society of America, last updated in 2009, but currently under review.

	Therapy		
Condition or treatment group	Primary	Alternative	Comments
Candidemia			
Nonneutropenic adults	Fluconazole 800-mg (12-mg/kg) loading dose, then 400 mg (6 mg/kg) daily or an echinocandin[a] (A-I). For species-specific recommendations, see text.	LFAmB 3–5 mg/kg daily; or AmB-d 0.5–1 mg/kg daily; or voriconazole 400 mg (6 mg/kg) bid for 2 doses, then 200 mg (3 mg/kg) bid (A-I)	Choose an echinocandin for moderately severe to severe illness and for patients with recent azole exposure. Transition to fluconazole after initial echinocandin is appropriate in many cases. Remove all intravascular catheters, if possible. Treat 14 days after first negative blood culture result and resolution of signs and symptoms associated with candidemia. Ophthalmological examination recommended for all patients.
Neutropenic patients	An echinocandin[a] or LFAmB 3–5 mg/kg daily (A-II). For species-specific recommendations, see text.	Fluconazole 800-mg (12-mg/kg) loading dose, then 400 mg (6 mg/kg) daily; or voriconazole 400 mg (6 mg/kg) bid for 2 doses then 200 mg (3 mg/kg) bid (B-III)	An echinocandin or LFAmB is preferred for most patients. Fluconazole is recommended for patients without recent azole exposure and who are not critically ill. Voriconazole is recommended when additional coverage for molds is desired. Intravascular catheter removal is advised but is controversial.
Suspected candidiasis treated with empiric antifungal therapy			
Nonneutropenic patients	Treat as above for candidemia. An echinocandin or fluconazole is preferred (B-III).	LFAmB 3–5 mg/kg daily or AmB-d 0.5–1 mg/kg daily (B-III)	For patients with moderately severe to severe illness and/or recent azole exposure, an echinocandin is preferred. The selection of appropriate patients should be based on clinical risk factors, serologic tests, and culture data. Duration of therapy is uncertain, but should be discontinued if cultures and/or serodiagnostic tests have negative results.
Neutropenic patients	LFAmB 3–5 mg/kg daily, caspofungin 70-mg loading dose, then 50 mg daily (A-I), or voriconazole 400 mg (6 mg/kg) bid for 2 doses then 200 mg (3 mg/kg) bid (B-I).	Fluconazole 800-mg (12-mg/kg) loading dose, then 400 mg (6 mg/kg) daily; or itraconazole 200 mg (3 mg/kg) bid (B-I)	In most neutropenic patients, it is appropriate to initiate empiric antifungal therapy after 4 days of persistent fever despite antibiotics. Serodiagnostic tests and CT imaging may be helpful. Do not use an azole in patients with prior azole prophylaxis.

Source: Clinical Practice Guidelines for the Management of Candidiasis: 2009 Update by the Infectious Diseases Society of America, 2009.

Triazoles (such as fluconazole) and echinocandins are the most commonly used empiric antifungals based on the literature we reviewed and our survey of infectious disease physicians. The triazoles, such as fluconazole, itraconazole, voriconazole, and posaconazole, have been shown to demonstrate similar activity against most *Candida* species, with each showing less activity against *C. glabrata* and *C. krusei*. Other classes of antifungals, such as the polyenes and flucytosine, have also shown strong efficacy. However the polyenes also have notable rates of treatment-related adverse events, such as nephrotoxicity, and

are more expensive. Flucytosine has demonstrated broad antifungal activity against most *Candida* species, with the exception of *C. krusei*, but has a short half life and is rarely administered as a single agent.

The 2009 guidelines for the treatment of candidiasis (currently under review) also suggest that although the susceptibility of *Candida* to the currently available antifungal agents is generally predictable if the species of the infecting isolate is known, individual isolates do not necessarily follow this general pattern and as such susceptibility testing is increasingly used to guide the management of candidiasis. This is especially important in situations where a patient does not respond to initial antifungal therapy. The committee noted that expert opinion suggests that laboratories perform routine antifungal susceptibility testing against fluconazole for *C. glabrata* isolates from blood and sterile sites and for other *Candida* species that have failed to respond to antifungal therapy or in cases where azole resistance is strongly suspected. However, currently, since antifungal resistance in *C. albicans* is uncommon, routine testing for antifungal susceptibility against this species is not generally recommended.

Exhibit 14: General Patterns of Susceptibility of Candida Species

Species	Fluconazole	Itraconazole	Voriconazole	Posaconazole	Flucytosine	Amphotericin B	Candins
Candida albicans	S	S	S	S	S	S	S
Candida tropicalis	S	S	S	S	S	S	S
Candida parapsilosis	S	S	S	S	S	S	S to R[a]
Candida glabrata	S-DD to R	S-DD to R	S-DD to R	S-DD to R	S	S to I	S
Candida krusei	R	S-DD to R	S	S	I to R	S to I	S
Candida lusitaniae	S	S	S	S	S	S to R	S

NOTE. I, intermediately susceptible; R, resistant; S, susceptible; S-DD: susceptible dose-dependent.
[a] Echinocandin resistance among *C. parapsilosis* isolates is uncommon.

Source: Clinical Practice Guidelines for the Management of Candidiasis: 2009 Update by the Infectious Diseases Society of America, 2009.

It was noted that the diagnosis of systemic fungal infection (usually candidiasis) in critically ill patients can be challenging, and rapid diagnostic methodologies, such as antigen and antibody detection assays, can be helpful in detecting candidiasis in the ICU patient. However, though these suggested tests have shown positive results significantly earlier than standard culture methods, false-positive reactions can occur with colonization alone, and their diagnostic utility in managing fungal infection in the ICU needs additional study. Finally, these guidelines noted that "several new diagnostic techniques offer promise for the early diagnosis of invasive candidiasis. Several of these assays are approved as adjuncts to the diagnosis of invasive candidiasis, but their role in clinical practice is poorly defined".

Hemostasis – T2HemoStat

Hemostasis, the arrest of bleeding from an injured blood vessel, is the body's normal physiological response to prevent or stop the loss of blood during an injury. Hemostasis is a complex process that is thought to include several steps, including: vascular spasm where the vessels' smooth muscle contracts, causing vasoconstriction; platelet plug formation, where platelets adhere to collagen fibers exposed in the vessel lining due to injury and release chemicals

that make other nearby platelets sticky; and coagulation, where a clot is formed.

When hemostasis is impaired, a patient is unable to promote the formation of blood clots to stabilize excessive bleeding. Impaired hemostasis can be a life-threatening condition, particularly in critical trauma patients where diagnostic results are typically required within minutes. Based on CDC data as published by the National Trauma Institute, each year trauma accounts for 41M emergency department visits and 2.3M hospital admissions in the U.S. Though each trauma patient can be different, we would estimate that a meaningful percentage of these patients have impaired hemostasis or are suspected of having impaired hemostasis post-initial blood transfusion.

Today, commonly used hemostasis diagnostics, such as platelet count, bleeding time, platelet aggregometry, clot based-assays such as Prothrombin Time (PT), and Activated Partial Thromboplastin Time (PTT) have various limitations. There is a growing body of literature supporting that these tests are inadequate for monitoring coagulopathy and guiding transfusion therapy in trauma patients and as a result point-of-care tests such as thromboelastography (TEG) and thromboelastometry (Rotem) have been adopted in many hospitals. Haemonetics' (HAE, Not Rated) TEG system and the ROTEM (made by ROTEM, a German company) are instruments that measure a patient's ability to form and maintain clots, providing information beyond what is provided by PT/PTT/INR tests, such as a patient's risk for hemorrhage or thrombosis. By providing a more complete picture of a patient's hemostasis system, clinicians may be able to better commence and/or discontinue the use of certain drugs, determine the likelihood of a patient's need for transfusion(s) and/or which blood components will be most effective.

These systems are based on a measure of the viscoelastic properties of the clot. There are numerous strengths associated with these technologies, such as: the ability to provide a rapid assessment of the overall coagulation status of the patient and various parameters which can be used to guide the administration of specific blood products, all three phases of coagulation are analyzed, transfusion algorithms based on the technologies have been shown to reduce rates of transfusion, the ability to detect a hypercoagulable state, and sensitivity to residual heparin. However, we believe some limitations also exist, including: poor ability to detect some conditions affecting platelet adhesion, somewhat limited utility in hypothermic patients, limited sensitivity to aspirin and clopidogrel, sample collection and processing methodologies that are deemed unstandardized by many clinicians and require highly skilled technicians, only moderate agreement between TEG and ROTEM devices, the requirement of multiple instruments (depending on testing volumes) and time required for full results sometimes taking 20-40 minutes, even with RapidTEG.

Lyme Disease

Lyme disease is a bacterial infection caused by *Borrelia burgdorferi*. *B. burgdorferi* is most commonly transmitted by deer ticks and black-legged ticks, which are typically found in wooded and grassy areas. Per the CDC, ~300,000 people are diagnosed with Lyme disease in the U.S. each year; this is 1.5x times the number of women diagnosed with breast cancer and six times the number of people diagnosed with HIV/AIDs. Additionally, the disease is found

in over eighty other countries and most experts believe the true number of cases is actually much higher than the reported numbers.

Experts often refer to Lyme disease as the "The Great Imitator" since its symptoms can mimic those of several other diseases, making it very challenging to diagnose. The symptoms significantly overlap with those of chronic fatigue, fibromyalgia, rheumatoid arthritis, multiple sclerosis, Parkinson's disease, ALS, depression, and Alzheimer's disease. Lyme disease can affect any organ of the body, including the brain and nervous system, muscles and joints, and the heart. Early signs and symptoms of Lyme disease include a rash and flu-like symptoms. The small bump that appears after a tick bite does not necessarily indicate Lyme disease; however, a few days post a tick bite, this redness may expand and form a distinct rash, called erythema migrans in a bulls-eye pattern. Estimates of what percent of patients develop such a rash vary widely, ranging from as low as 20% to as high as 80%.

When detected and treated early with antibiotics, recovery can occur relatively quickly. The earlier the treatment starts, typically, the more complete the treatment is. If Lyme disease is not diagnosed and treated early and/or the treatment is inadequate, the disease can progress into a chronic condition. Current lab tests for Lyme disease can be used to identify antibodies to the bacteria, but have limited utility. The ELISA test is used most frequently to detect antibodies to *B. burgdorferi*, but is not used as the sole basis for diagnosis, since false-positive results occur frequently. When the ELISA test is positive, a Western blot, which detects antibodies to several proteins of B. *burgdorferi* is usually performed to confirm the diagnosis. Since it takes time for the body to develop antibodies, generally these tests have limited reliability until a few weeks after infection. Additionally, these tests can take weeks to show a positive result and cannot distinguish between new infection and prior infection. Despite the limitations of current tests for Lyme disease, it is estimated that over 3.4M tests are performed annually in the U.S., at an estimated cost of $400M+. We believe there is a significant need for an assay to detect Lyme disease within days after a tick bite, to detect infection when a rash is absent and/or antibody testing comes back negative, and to determine whether the bacteria has cleared post-treatment.

Understanding the Space

We spent time with numerous physicians (within both infectious disease and critical care) and clinical microbiology lab directors. Though we note that workflow and protocols vary from hospital to hospital and lab to lab, these discussions led to us to develop the below general overview of the space.

When a bloodstream infection is first suspected, a physician will order a blood culture. For perspective, Brigham and Women's Hospital, a ~800 bed hospital, runs about 50k blood cultures each year, while the West Haven Campus of the Connecticut VA System (~215 beds) runs about 10k blood cultures a year. Blood culture involves a blood draw (very routine) where typically ~20mL or more of blood is drawn via multiple (at least two) draws. Most adults undergo two 10mL blood draws whereas for children and babies the amount drawn depends on the patient's weight and other factors. Once drawn, the blood is placed into at least two blood culture bottles, which contain nutrients that have been formulated to encourage the growth of bacteria and fungi.

The most commonly used blood culture systems today are sold by bioMérieux (BIM, Not Rated) (the BacT/ALERT), Becton, Dickinson and Co. (BDX, Not Rated) (the BACTEC), and Thermo Fisher Scientific Inc. (TMO, Neutral, Analyst: Dane Leone) (the VersaTREK). Per our channel checks, it costs ~$20-30 to run a negative blood culture. For blood cultures that turn positive, the additional cost of the full organism workup (Gram stain, additional sub-culturing, identification, susceptibility/resistance profiling) increases meaningfully and ranges from $60 - $300 on average depending on how many and which organisms are present, how manual the identification and susceptibility/resistance assays are (manual subculturing -- cheaper and slower vs. various automated assays -- more expensive, but faster), how much confirmatory testing is necessary, etc. We estimate the cost of a full workup post-positive blood culture is likely in the $100-250 range for most high-volume hospital labs that have adopted various automated platforms for identification and susceptibility/resistance testing.

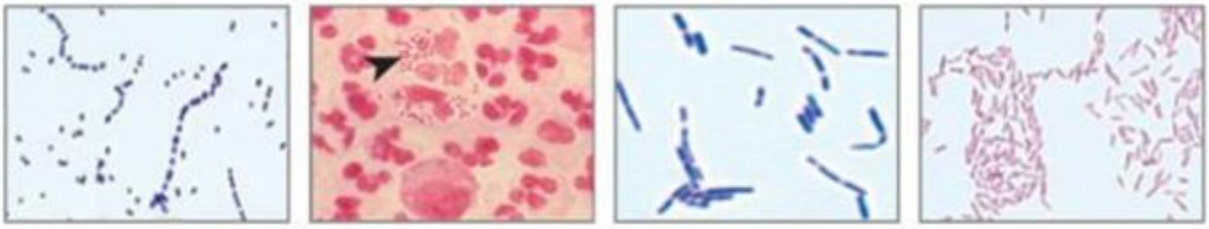
True and false positive rates for blood culture vary, but are generally estimated around ~5-10%, meaning that when a positive result occurs (about 5-10%) of the time, there is an estimated 50% chance that the result is a true bacteraemia vs. a contaminant. Furthermore, blood culture cannot distinguish a positive result due to the presence of bacteria or fungi. Since the initial concentration of a pathogen among patients with a bloodstream infection is usually ~10 CFU/mL and growth of the organism must reach a concentration of 1,000,000 to 100,000,000 CFU/mL for a BC to turn positive, it can sometimes take 2-5 days for the lab to report a positive result. In cases where a patient is septic or developing sepsis, we estimate the time to positive blood culture is more like ~8-12 hours. A negative BC test result requires a minimum of five days. Notably, various studies have estimated that less than 15% of organisms discovered via blood culture are clinically relevant. Per UptoDate, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *group A streptococci, Enterobacteriaceae, Haemophilus influenzae, Pseudomonas aeruginosa, Bacteroidaceae*, and *Candida* species are always considered important clinical pathogens, while *Viridans streptococci* and *enterococci* may reflect either true pathogens or contaminants. Finally, an estimated 6-18% of bloodstream infections are polymicrobial, meaning multiple microorganisms are present.

When a blood culture is positive, additional processes/assays must be performed to identify the organism/pathogen to determine whether the organism is a contaminant vs. a clinically relevant organism and so that specific targeted drug therapy can be provided. Typically, a Gram stain is the first test performed post-positive BC. The Gram stain has been around for over 100 years and continues to be one of the most important staining techniques in microbiology. Gram staining is used to differentiate between two large groups of bacteria (Gram-positive and Gram-negative) based on the differing physical properties of their cell walls. Gram stain results typically include a description of what was seen on the slide, including:

1) Whether the bacteria are Gram-positive (purple) or Gram-negative (red/pink)
2) Shape – round (cocci) or rods (bacilli)
3) Size, relative quantity and/or arrangement (clusters vs. strings)

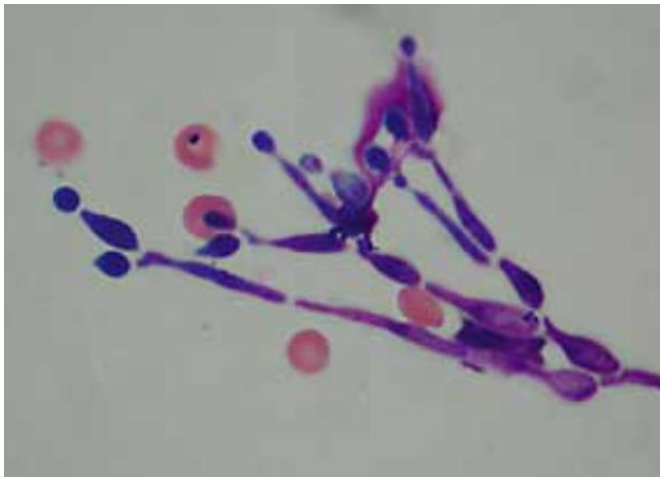
4) The presence of yeast (in the form of yeasts or molds). Yeast can appear as single cells, with or without buds, while molds may appear with plant-like branches, called hyphae.

Exhibit 15: Example of a Few Medically Significant Bacteria and How They Look on a Gram Stain (left to right: Gram-positive cocci, Gram-negative cocci; Gram-positive bacilli, Gram-negative bacilli)



Source: Lab Tests Online Website

Exhibit 16: *Candida albicans* under Gram Stain



Source: UCSF Lab Website

Gram stain results often help a microbiologist determine how the organism(s) should be sub-cultured and which test(s) to perform next – including identification of the organism(s) and what drug(s) should be used to fight it/them. There are dozens of manual testing methods that can be used to identify bacteria, including: phenol red fermentation, starch hydrolysis, lipid hydrolysis, casein hydrolysis, gelatin hydrolysis, catalase testing, oxidase testing, the sulfur reduction test, motility testing, and hemolysis testing to name a few. Since the identification of most species of bacteria via this manual method is labor intensive and slow, over time automated platforms have been introduced within clinical microbiology labs to speed up the identification process and provide more accurate results.

Some of these automated systems operate off a positive blood culture sample, while others require the organism detected via blood culture to be sub-cultured prior to identification and the determination of susceptibility and resistance. During the sub-culturing process, a blood culture or respiratory sample is streaked onto the surface of several types of culture media, usually contained in a petri dish. This media is incubated (usually overnight) and then examined for the presence of bacteria or yeast. Since many of the current automated systems require a pure isolate, if more than one type of organism is

present, each unique colony must extracted and streaked onto a separate petri dish which may contain the same or a different growth media. These dishes are then incubated again (usually overnight). If the growth post this second incubation reveals single isolated organisms, the analysis can begin on these cultures.

Today, there are several fully or partially automated instruments and assays used in the identification process – some are based on traditional phenotypic methods, while others are based on molecular or chemotaxonomic methods.

Phenotypic methods of identification consider the bacteria's growth characteristics, biochemical profile, Gram stain, etc. and can be performed manually (tests listed above) or via automation.

Molecular methods look at the organism's DNA and/or RNA. Common molecular technologies for microorganism identification include polymerase chain reaction (PCR), sequencing, and microarrays. Each of these technologies have tradeoffs when it comes to labor required, cost, speed, breadth, and sensitivity/specificity.

Conventional PCR has been around for several years and involves multiple steps. First, DNA is extracted from the sample. This is typically done by heating with a detergent that lyses bacterial cells and releases DNA. Next, the PCR reaction begins. During this reaction, heat is first used to denature the DNA into single strands and then a reduction in temperature allows two primers (short artificial single-stranded DNA sections that are designed to be complementary to specific parts of a target sequence) to bind. The temperature is then raised again and the DNA-polymerase enzyme catalyzes the duplication of the target sequence. This temperature cycle is then repeated at least 30 times to produce a quantity of DNA that is sufficient for detection, which is the next step of the PCR process. During this step, gel electrophoresis is usually used to visualize the amplified product. The drawbacks to using PCR include: 1) background noise (due to the amplification process and high sensitivity, any contamination within the sample has the potential to lead to false results); 2) primers must be specifically designed based on knowledge of the target organism(s) genome and many microbial genomes often contain unexpected mutations; and 3) speed (to some extent).

The use of real-time PCR has grown rapidly in the microbiology field given its sensitivity, specificity, relative simplicity, low contamination risk and speed. During real-time PCR, PCR chemistry and fluorescent probe detection of the amplified product occurs in the same closed reaction vessel. This limits sample contamination, requires less hands-on time, is faster (reduced cycle times, lack of separate post-PCR detection procedures), is much simpler, and is more sensitive (can utilize fluorescence to detect the amplified product at a smaller size).

Chemotaxonomic methods of organism identification, such as MALDI-TOF (Matrix Assisted Laser Desorption Ionization Time-of-Flight), ESI-MS (Electrospray Ionization Mass Spectrometry), spectroscopy, and others classify organisms via various chemical markers, such as cell wall components, lipids, proteins, etc. MALDI-TOF has become a popular technology for the identification of organisms in the clinical setting since the first platforms were approved for this use in 2013. To identify an organism via MALDI-TOF, first the organism is embedded into a matrix. The matrix + organism is then hit with laser energy. When this occurs, the matrix serves to protect the microbial

proteins, convert the laser energy into excitation energy, and helps desorb and ionize microbial proteins. The ionized analytes then enter a tube where they are separated by their individual mass-to-charge ratios. Based on this information, a mass spectrum is created and compared to a robust library of spectra of known organisms.

Based on our diligence, currently the most commonly used multiplex platforms (in no particular order) for microbial identification only and/or microbial identification and susceptibility/resistance testing include those discussed below. Some labs we spoke with have and use multiple systems for various reasons – speed, sensitivity, cost, patient population, staffing, and even personal preference.

Mass Spec/MALDI-TOF – identification – Bruker's (BRKR, Buy, $25 PT, Analyst: Dane Leone) Biotyper System and bioMerieux's Vitek MS System: MALDI-TOF was mentioned positively by nearly all of the clinicians we spoke with. One lab director even discussed the belief that labs servicing smaller hospitals (as small as 250 beds) could benefit and have a positive ROI with a MALDI investment. The benefits of MALDI-TOF include: 1) very low cost per sample (under $1 post initial capital investment); 2) speed (can identify organisms in a matter of minutes), and 3) breadth and adaptability (the libraries of both systems were described to us as essentially "unlimited"; both of which can be updated over time). Various studies from around the world have shown genus-level identifications of 96-99% and species-level identifications of 85-97%.

We believe the limitations of MALDI-TOF today include 1) the initial capital investment ($150-200k); 2) footprint (think soda machine standing upright or on its side depending on the system); 3) lack of susceptibility/resistance testing (though the technology may eventually be able to detect some antibiotic resistance mechanisms and integrated solutions with other platforms are available), and 4) the requirement of a positive blood culture AND the sub-culturing of specific organisms for a minimum of 4-6 hours post-positive blood culture to ensure a pure strain is isolated for analysis and that enough organism is present for analysis.

Bruker's Biotyper System can be integrated for use with Danaher's (DHR, Buy, $105 PT, Analyst: Dane Leone) MicroScan WalkAway plus Microbiology System, enabling both ID and AST testing with a simple workflow. bioMerieux's VITEK MS can be integrated with the company's Myla (middleware) and the VITEK 2 System for microbial identification and AST testing.

During our conversations with lab directors, we did not hear a clear preference towards one MALDI system vs. the other, with most stating that both are good systems with decisions on which to adopt being as simple as which system has the more ideal footprint for the lab's current configuration. Though we believe potential advantages of bioMerieux's system over Bruker's initially included 1) being first to the U.S. market (approved August 2013 vs. November 2013), and 2) bioMerieux having a broader label (initially approved for the "identification of bacteria and yeasts that are known to cause serious illness in humans" vs. Bruker's initial FDA claim of "the identification of Gram-negative bacterial colonies cultured from human specimens"). However, since BRKR obtained an expanded claim in April 2015 that includes an additional 170 species and

species groups, including aerobic Gram-positives, fastidious Gram-negatives, *Enterobacteriaceae*, and anaerobic bacteria and yeasts), the playing field seems relatively level.

Nanosphere's (NSPH, Not Rated) Verigene BC-GP (Gram-positive) and BC-GN (Gram-negative) – identification, plus some resistance markers: NSPH's Verigene platform utilizes qualitative, multiplex assays for the detection of specific nucleic acid targets in a microarray format using capture and mediator oligonucleotides for gold nanoparticle probe-based endpoint detection. Nanosphere currently has two approved panels for bloodstream infections, the Verigene Gram-Positive Blood Culture Test, (BC-GP) and the Verigene Gram-Negative Blood Culture Test (BC-GN) and one panel in development, the Verigene Yeast Blood Culture (BC-Y) Test. The BC-GP test can provide bacterial identification (species) information for 9 targets, bacterial identification (genus) information for 3-4 targets (3 in the U.S., 4 OUS), and resistance information for 3 targets within ~2.5 hours of positive blood culture. The BC-GN test can provide identification (species) for 4-5 targets (4 in the U.S.; 5 OUS), identification (genus) information for 4 targets and resistance information for 6 targets within ~2 hours of positive blood culture. Though still in development, the BC-Y test is expected to provide identification (species) for 5 *Candida* targets and 3 *Cryptococcus* targets within approximately two hours of positive blood culture. Per our channel checks, the cost per test is ~$60-80.

bioMerieux's/BioFire FilmArray System – identification, some resistance genes: The FilmArray System extracts and purifies all nucleic acids from the sample, performs a nested multiplex PCR, a second-stage PCR reaction to detect the products from the first stage PCR and endpoint melting curve data to generate a result for each target in a single report. The FilmArray system is FDA approved, CE marked and TGA certified and "enables simultaneous testing for bacteria, viruses, yeast, parasites and/or antimicrobial resistant genes" via these three approval panels. The FilmArray Respiratory Panel tests for 20 respiratory viruses and bacteria. The FilmArray Gastrointestinal Panel tests for 22 common gastrointestinal pathogens including viruses, bacteria and protozoa that cause infectious diarrhea and the FilmArray Blood Culture Identification Panel tests for 24 pathogens and 3 antibiotic resistance genes associated with bloodstream infections. The FilmArray Blood Culture Identification Panel operates off a positive blood culture sample and the extraction, amplification and detection occurs in one closed system. With the FilmArray System, all targets/analytes are included on one panel vs. the Verigene Platform which utilizes separate panels. Per our channel checks, the cost per test is ~$120-150 and the average turnaround time is ~1.5-2 hours.

bioMerieux's VITEK 2 – identification and antibiotic susceptibility testing: For identification, the VITEK 2 reagent cards have individual test substrates that measure various metabolic activities and record the test reaction results. This data is then compared to the system's database to determine the microorganism's identification. Advanced Colorimetry, an identification technology is also used to discriminate between species and limit the rate of misidentified species. The principle of the VITEK 2 AST cards is based on the microdilution minimum inhibitory concentration (MIC) technique enabling a miniaturized, abbreviated and automated version of the doubling dilution technique. The VITEK 2 requires cultured isolates for testing and can be integrated with the VITEK MS.

BDX's Phoenix System – identification and antibiotic susceptibility testing: BDX's Phoenix Automated Microbiology System provides identification and/or susceptibility information on organisms detected post-positive blood culture. This system allows for 1 to 100 ID/AST determinations to be performed simultaneously. For identification, the Phoenix ID panels include various metabolic tests as well as chromogenic and fluorogenic substrates as well as single carbon source substrates in the identification of organisms. Susceptibility testing with Phoenix is similar to VITEK 2's AST testing and includes a modified miniaturized version of the micro-broth doubling dilution technique and the determination of bacterial growth in the presence of various concentrations of the antimicrobial agents. Only pure culture isolates can be used for testing on the Phoenix.

Danaher/Beckman Coulter's MicroScan WalkAway plus System - identification and antibiotic susceptibility testing: In 2014, Beckman Coulter, an indirect wholly-owned subsidiary of Danaher Corporation, acquired the clinical microbiology business of Siemens Healthcare Diagnostics, including the MicroScan WalkAway plus System, a 4th generation system that identifies microorganisms and performs susceptibility testing. Also owned by Beckman Coulter, the autoSCAN-4 System, marketed more for small-capacity laboratories or backup testing, can provide bacterial identification and susceptibility information. In the U.S., several panel formats are currently available for use on the MicroScan instruments, including: conventional overnight panels, rapid ID panels, ESβL plus panels, MICroSTREP plus panels, and specialty ID panels. Finally, the MicroScan System can be paired with DHR's Copan WASP: Walk-Away Specimen Processor and the Bruker MALDI Biotyper System. Similar to the ID/AST Systems discussed above, the MicroScan interprets biochemical results through the use of a photometric or fluorogenic reader for the identification of organisms. For AST, the system also utilizes the direct minimum inhibitory concentration (MIC) susceptibility methodology, though the company's PROMPT inoculation method for isolates is thought to reduce inoculum preparation time by over 40% vs. other turbidity methods.

All of these ID/AST systems have similar limitations, including: speed to result (esp. when including sub-culturing time and time to positive blood culture), the requirement of up-front processing/culturing (not direct from blood culture sample), and lab space (these are large instruments).

Please see our competition section for details on emerging technologies in the clinical microbiology space.

Company Overview

T2 Biosystems is an in vitro diagnostics company focused on developing various diagnostic products to improve patient health. The company's proprietary T2 Magnetic Resonance Platform, or T2MR, enables the rapid detection of pathogens, biomarkers, and other abnormalities in a variety of unpurified patient sample types, including whole blood, plasma, serum, saliva, sputum and urine. T2MR uses a miniaturized, magnetic resonance-based approach that measures how water molecules react in the presence of magnetic fields. For molecular and immunodiagnostics targets, nanoparticles coated with target-specific binding agents are introduced to the sample. If the target is present, the nanoparticles bind and cluster around it. The result is a

disruption of the surrounding water molecules and an altered magnetic resonance signal, which can be measured to identify what target(s) is/are present in the sample.

Current data supports detection as low as one colony forming unit per milliliter, or CFU/mL with the T2MR platform. T2's initial development efforts are focused on the use of the T2MR technology within sepsis, hemostasis, and Lyme disease.

Current Products

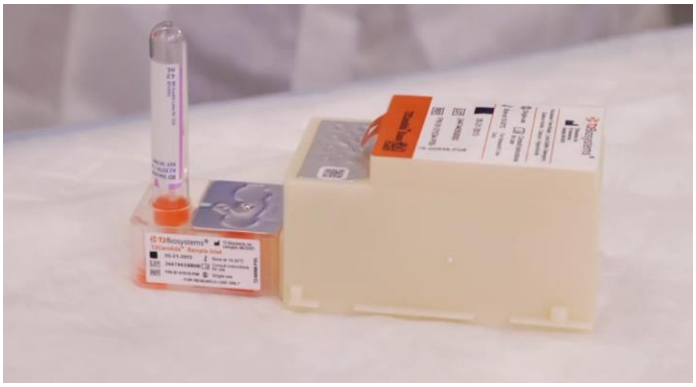
T2 currently has two products cleared for use in the U.S. and Europe – the T2Dx Instrument and the T2Candida Panel. The T2Dx Instrument (shown below) is a fully automated, benchtop instrument. To operate the T2Dx, a patient's sample tube is snapped onto a disposable test cartridge that had been pre-loaded with reagents. The cartridge is then inserted into the instrument, where it is automatically processed. After the sample has been processed, the test results are displayed on the instrument's screen or transmitted directly to a lab information system. Notably, the T2MR technology and T2Dx instrument do not require sample purification, nor analyte extraction, unlike other technology platforms commonly used in microbiology labs. The T2Dx can process up to seven specimens simultaneously.

Exhibit 17: T2 Biosystems' T2Dx Instrument

Source: T2 Biosystems Website

The T2Candida Panel is run on the T2Dx instrument and together the instrument and panel can detect species-specific *Candida* directly from whole blood in ~3-5 hours.

Exhibit 18: T2 Biosystems' T2Candida Cartridge with Patient Sample



Source: T2 Biosystems Website

Sales, Marketing, Pricing, Reimbursement, Manufacturing and Intellectual Property

Sales, Marketing, Pricing & Reimbursement

In August 2014, T2 hired two sales reps and by the end of November 2014 the company had a total of seven sales reps. In 4Q14, T2 commenced commercialization efforts of the T2Dx Instrument and the T2Candida Panel, with its first U.S. placement occurring in 1Q15.

As of the end of 1Q15, the company had nine reps and reiterated plans to grow the sales team to 15 people by the end of 2015. This sales team will initially target the top 450 hospitals in the United States that have the highest concentration of patients at risk for *Candida* infections. Per the company, these 450 hospitals represent about a third of the ~$1.3B T2Candida annual market opportunity. On the 4Q14 earnings call in February 2015, mgmt communicated that the company was "engaged at some level" with ~25% of these target hospitals. On the 1Q15 call in May 2015, mgmt stated that 25 high-volume hospitals had completed an in-depth ROI analysis; this compared to ~9 high-volume hospitals being at this stage when the company communicated its progress on the 4Q14 call. Since the company's first earnings call in November 2014, mgmt has communicated a goal of making placements in "30 or so" of these high-volume target hospitals by the end of 2015. Despite signing only one contract within this group of U.S. hospitals in 1Q15, mgmt feels the company is on track to reach 30 by year end with 60% or more of these 30 placements occurring in 2H15.

T2 plans to place instruments either on reagent rental or through capital sales, with an approximate split of 80%/20%, respectively. Outside the U.S., we would expect this split to be closer to 50%/50%. Per our discussions with U.S. clinicians, we believe T2Candida is being priced at ~$200 - $250/test with the T2Dx instrument priced at ~$150k if purchased outright.

We believe the costs associated with running T2's T2Candida Panel would fall under existing reimbursement codes, specifically DRG codes used for patients hospitalized due to an agent causing sepsis and/or other conditions. In the T2Candida pivotal trial, ~48% of the patients were classified as

"immunocompromised due to cancer, a transplant, or other" and the remaining 52% were classified as "critical care and related conditions".

T2 obtained CE mark for the T2Dx and T2Candida Panel via an EC Declaration of Conformity (the type of confirmatory assessment that can be performed internally for low-risk devices) in July 2014. Outside the U.S., we expect the company to utilize distributors for the sale of the instrument and panel(s).

Manufacturing

T2 manufactures the T2Dx instrument and T2Candida reagent trays at its manufacturing facility in Wilmington, MA. The manufacturing of the T2Candida consumable cartridge is outsourced to a contract manufacturing organization and the particles are supplied by GE Healthcare (GE, Not Rated).

Intellectual Property

T2 is the owner or licensee of over 50 patents and ~60 patent applications, per the company's last 10-K. The patent families are mainly focused on the protection of various attributes of the company's assay architecture and the instrumentation used for the T2Candida, T2Bacteria, and T2Lyme panels. Certain aspects of the conduct of the assays and the detection of analytes are also protected via these patent families. The company owns several patent families covering aspects of the T2HemoStat assay, including the assay's architecture and the conduct of the analysis.

Issued patents within the patent families that cover T2Candida and T2Bacteria are expected to expire between 2023 and 2031, while some pending applications among these same families would extend to 2033 (if issued). The patents covering T2HemoStat are expected to expire between 2026 and 2035, if issued. Finally, the patent family covering T2Lyme, if issued, is expected to expire in approximately 2035.

License Agreements

Massachusetts General Hospital: T2 entered into an exclusive licensing agreement with MGH in 2006 (the agreement has been amended twice since, in 2008 and 2011); at this time T2 paid MGH an upfront fee and issued a low-single-digit percentage of the company's then-outstanding common stock. As part of this agreement, T2 has "an exclusive, worldwide, sublicensable license under certain patent rights to make, use, import and commercialize products and processes for diagnostic, industrial and research and development purposes". This agreement also requires T2 to: "use reasonable commercial efforts to develop and make available to the public products and processes covered by the agreement, and to achieve specified organizational, development and commercialization milestones by specified dates", reimburse MGH costs associated with prosecution and maintenance of the patent rights licensed, make payments to MGH upon the achievement of specified regulatory milestones, pay an annual license maintenance fee, and pay low-single-digit royalties to MGH on net sales of products and processes covered by the licensed patent rights.

Products and processes covered under this agreement include: T2Candida, T2Bacteria, and other particle-based T2MR panels that may be developed in

the future. T2's obligation to pay royalties for these will end upon the expiration of the patent rights licensed or ten years after the first commercial sale of the first product or process in a particular category, whichever comes later.

In addition to the above, should T2 choose to sublicense the patents licensed from MGH, the company must pay MGH a low double-digit percentage of specified gross revenue received from the sublicense(s). Finally, T2 is required to pay MGH royalties of less than 1% on net sales of specified products and processes that are not covered by the patent rights licensed under this agreement; these obligations will expire 12 years post the first commercial sale of such product/process or in the event MGH terminates all of the licenses granted to T2 under the agreement.

Clinical Data

direcT2 Clinical Trial - Published in *Clinical Infectious Disease*, January 2015

T2 conducted a multi-center pivotal clinical trial for the T2Dx Instrument and T2Candida Panel in 2013/2014. This trial included two patient arms, 1) the Prospective Arm (1,501 samples; patients with a possible infection) and 2) the Contrived Arm (300 samples, of which 250 patient specimens were labeled contrived because each contained a known quantity of *Candida* CFUs and 50 were specifically known not to contain *Candida*). The positive contrived samples were prepared by spiking clinical isolates into individual patient specimens at concentrations determined to be equivalent to the clinical state of patients presenting with symptoms of a *Candida* infection based on publications and discussions with FDA. Additionally, 20% of the positive contrived samples were spiked with concentration levels of less than 1 CFU/mL.

All samples were prepared and run in a blinded manner at the same clinical sites that processed the prospective samples. This trial evaluated the sensitivity (% of results that agree with a reference method for positive results) and specificity (% of results that agree with reference method for negative results) of T2Candida on the T2Dx instrument. In this trial, the Prospective Arm was compared to blood culture and the Contrived Arm was compared to the known (present or absent) state with the following results reported:

-Specificity of T2Candida vs. Candida negative blood culture results (from specimens in the Prospective Arm)

-Specificity of T2Candida vs. Candida negative samples (from specimens in the Contrived Arm)

-Sensitivity of T2Candida vs. known Candida-positive specimens (collected from patients in the Contrived Arm)

-Sensitivity of T2Candida vs. Candida-positive blood culture results (from positive blood culture results from patients in the Prospective Arm).

Data from the direcT2 were as follows with results from the study published in *Clinical Infectious Disease* in 2015 in an article entitled: T2 Magnetic Resonance Assay for the Rapid Diagnosis of Candidemia in Whole Blood: A Clinical Trial.

Exhibit 19: Data from T2's direcT2 Clinical Trial

T2Candida Performance Characteristics		
	Overall Sensitivity	**Overall Specificity**
Number of Tests (%)	**234/257 (91.1%)**	**5114/5146 (99.4%)**
A/T (C. albicans/C. tropicalis)	96/104 (92.3%)	1679/1697 (98.9%)
P (C. parapsilosis)	49/52 (94.2%)	1736/1749 (99.3%)
K/G (C. krusei/C. glabrata)	89/101 (88.1%)	1699/1700 (99.9%)
Total	**234/257 (91.1%)**	**5114/5146 (99.4%)**
	Sensitivity	**Specificity**
Prospective Tests:		
A/T (C. albicans/C. tropicalis)	2/4 (50.0%)	1479/1497 (98.8%)
P (C. parapsilosis)	2/2 (100.0%)	1487/1499 (99.2%)
K/G (C. krusei/C. glabrata)	1/1 (100.0%)	1499/1500 (99.9%)
Total	**5/7 (71.4%)**	**4465/4496 (99.3%)**
Contrived Tests:		
A/T (C. albicans/C. tropicalis)	94/100 (94.0%)	200/200 (100.0%)
P (C. parapsilosis)	47/50 (94.0%)	249/250 (99.6%)
K/G (C. krusei/C. glabrata)	88/100 (88.0%)	200/200 (100.0%)
Total	**229/250 (91.6%)**	**649/650 (99.8%)**

T2 Candida Limit of Detection		Sensitivity Sub-Analysis: Sensitivity by Species Relative to LoD	
Species	**Final LoD (CFU/mL.)**	**≥ LoD (Sensitivity)**	**< LoD (Sensitivity)**
C. albicans	2	39/39 (100.0%)	9/11 (81.8%)
C tropicalis	1	38/40 (95.0%)	8/10 (80.0%)
C. parapsilosis	3	32/32 (100.0%)	15/18 (83.3%)
C. glabrata	2	35/37 (94.6%)	7/13 (53.8%)
C. krusei	1	40/40 (100.0%)	6/10 (60.0%)
Total		**184/188 (97.9%)**	**45/62 (72.6%)**

Time to species identification or negative result for T2MR and Blood Culture		
	Blood Culture	**T2Dx**
Time to Results (hours):		
Mean ± SD (N)	126.5 ± 27.3 (1470)	4.2 ± 0.9 (1470)
Median	121	4.1
(Min, Max)	(12.4, 247.2)	(3.0, 7.5)
Time to Positive Results[1,2] (hours):		
Mean ± SD (N)	43.6 ± 11.1 (4)	4.4 ± 1.0 (4)
Median	46.1	4.6
(Min, Max)	(28.1, 54.1)	(3.2, 5.4)
Time to Negative Results[1,2] (hours):		
Mean ± SD (N)	126.7 ± 27.0 (1466)	4.2 ± 0.9 (1466)
Median	121.1	4.1
(Min, Max)	(12.4, 247.2)	(3.0, 7.5)

Notes: 1 = Includes samples that are 100% concordant for both methods (i.e. does not include discordant results).; 2= Refers to time to species identification or final negative result.

Sensitivity Sub-Analysis: Sensitivity by Titer Level				
Species	<1 CFU/ml Sensitivity	1 — 10 CFU/ml Sensitivity	11 — 30 CFU/ml Sensitivity	31 — 100 CFU/ml Sensitivity
C. albicans	8/10 (80.0%)	18/18 (100.0%)	17/17 (100.0%)	5/5 (100.0%)
C tropicalis	8/10 (80.0%)	16/18 (88.9%)	17/17 (100.0%)	5/5 (100.0%)
C. parapsilosis	8/10 (80.0%)	17/18 (94.4%)	17/17 (100.0%)	5/5 (100.0%)
C. glabrata	5/10 (50.0%)	16/18 (88.9%)	16/17 (94.1%)	5/5 (100.0%)
C. krusei	6/10 (60.0%)	18/18 (100.0%)	17/17 (100.0%)	5/5 (100.0%)
Total	**35/50 (70.0%)**	**85/90 (94.4%)**	**84/85 (98.8%)**	**25/25 (100.0%)**

Sensitivity Sub-Analysis: Sensitivity by Species Relative to Clinically Relevant Concentrations			
Species	Clinically Relevant Concentration	Sensitivity < Relevant CFU	Sensitivity > Relevant CFU
C. albicans	1-10 CFU/mL	80.0%	100.0%
C tropicalis	1-10 CFU/mL	80.0%	95.0%
C. parapsilosis	11-30 CFU/mL	89.3%	100.0%
C. glabrata	11-30 CFU/mL	75.0%	96.0%
C. krusei	11-30 CFU/mL	85.7%	100.0%
Total		**82.7%**	**98.0%**

Other Notable Findings:
-Within the Prospective Arm, T2Candida accurately detected a rare co-infection in one study patient with C. albicans and C. parapsilosis in their bloodstream. -T2Candida detected at least one infection that was not identified by blood culture, which was determined to be a Candida infection seven days after the T2Candida result was obtained. -T2Candida has a negative predictive value of 99.8% in a standard population.

Source: TTOO SEC Filings, Clinical Infectious Disease, 2015

In addition to this trial, T2 collected data from an analytical verification study to determine the limit of detection for each species identified by the T2Candida Panel. This limit of detection was defined as the lowest concentration of *Candida* that can be detected in 95% of at least 20 samples tested at a single concentration. Finally, we provide a summary of other notable publications below.

Exhibit 20: Other Notable Publications

Other Notable Publications:
T2Candida Provides Rapid and Accurate Species Identification in Pediatric Cases of Candidemia
Poster presented at ASM 2015; first author from Icahn School of Medicine, Mount Sinai Hospital -The T2Candida Panel accurately identified each species of Candida isolated from blood culture (BC) in each pediatric patient; time to result was 3-5 hours vs. 2-5 days with BC. -T2Candida yielded a sensitivity of 91.1% (vs. 38-50% with BC), specificity of 99.4% (97%), PPV of 81.8% (21%), NPV of 99.7% (99.2%).
T2 Magnetic Resonance Enables Nanoparticle-Mediated Rapid Detection of Candidemia in Whole Blood
Science Translational Medicine (2013)
-T2MR was tested across 320 contrived whole blood samples, each containing one of the five clinically relevant species of Candida, and was able to detect each of the species at an LoD ranging from 1 to 3 CFU/mL. -T2MR was tested across 24 whole blood specimens from patients exhibiting symptoms of sepsis, with eight Candida positive, eight bacteria positive and eight negative samples. Results showed 100% sensitivity and 100% specificity of T2MR when compared with blood culture results for identification of Candida. -In patients with Candida treated with antifungal therapy, T2MR detected the presence of Candida in patient samples drawn up to four days after antifungal administration, while blood culture failed to identify the infection upon administration of antifungal
Comparison of the T2Dx Instrument with T2Candida Diagnostic Panel and Automated Blood Culture in the Detection of *Candida* Species Using Seeded Blood Samples
Diagnostic Microbiology and Infectious Disease (2013)
-T2Candida detected all of the samples of C. glabrata at concentrations of 2.8 CFU/mL, while blood culture was not able to detect C. glabrata in any of the samples, even at a higher concentration of 11 CFU/mL and with the standard five-day run time. -T2Candida detected all of the samples for all of the species of Candida at concentration levels of 3.1 to 11 CFU/mL. -The average time to species identification was approximately three hours for T2Candida, as opposed to over 60 hours for blood -In contrived blood samples at concentrations between 3.1 — 11 CFU/mL, sensitivity was 100% and specificity was 98%.

Source: TTOO SEC Filings, BTIG Research

Pipeline Products

With commercialization of the T2Candida Panel underway, T2 is working on its next three products: T2Bacteria, T2Stat + T2HemoStat, and T2Lyme.

T2Bacteria

Data for the T2Bacteria Panel seems mainly limited to internal company data at this time. We believe the company has demonstrated feasibility of the technology based on this internal data given the company has already had pre-IDE communications with FDA. The T2Bacteria Panel is designed to run on the same instrument as T2Candida. The T2Bacteria Panel will detect specific bacterial species directly from whole blood in three to five hours, with limits of detection as low as one CFU/mL.

The company plans to initiate clinical trials for T2Bacteria by the end of 2015 and mgmt expects the U.S. clinical trial and FDA-clearance criteria to be comparable to what was seen with T2Candida. We currently model a U.S. launch of the T2Bacteria Panel commencing in 2Q17.

T2HemoStat

T2 believes that the T2Stat instrument and T2HemoStat Panel will be able to provide hemostasis measurements such as clotting time, platelet activity, clot contraction, and clot lysis in under 20-45 minutes from clinical samples as small as a finger stick of whole blood on a small, tabletop easy-to-use system that does not require highly skilled technicians for its operation. We note that T2's filings say "under 45 minutes", yet on the 4Q14 earnings conference call, mgmt said "in 20 minutes or less".

The use of the T2Stat and T2HemoStat will be focused initially on the unmet need for trauma patients. However, over time T2 hopes to develop additional diagnostic tests to be used in a broader population of patients with impaired hemostasis.

Proof-of-concept data for T2's hemostasis platform was published in *Clinical Chemistry* in 2014. Clotting, clot contraction, and fibrinolysis stimulated by thrombin or tissue plasminogen activator, respectively, were measured and T2MR signals of clotting samples were compared with images produced by scanning electron microscopy and with standard reference methods for the following parameters: hematocrit, prothrombin time, clot strength, and platelet activity. Though we admit this data is early, it seems this technology has the potential to provide accurate measurements of hematocrit, clotting time, platelet reactivity, and clot strength. Furthermore, this data suggests that the T2MR technology may provide some insight in platelet health, which could be useful in the monitoring of aspirin and other antiplatelet therapies.

The company plans to initiate a FDA pivotal trial for T2HemoStat in 1H2016.

T2Lyme

The T2Lyme Panel is being developed to directly direct the bacteria that causes Lyme disease (*B. burgdorferi)* from a patient's blood. This panel is expected to be run on the same T2Dx instrument used for the T2Candida and T2Bacterial panels. Based on the T2MR technology and the advantages the

technology provides, T2 anticipates that the T2Lyme Panel will have high sensitivity, high specificity, ease of use, and a rapid time to result, which will enable a timely and accurate diagnosis of Lyme disease, particularly in the disease's early stages.

Today, serology is the most commonly used diagnostic method for Lyme disease. PCR-based assays for Lyme disease are also currently being used in some cases, since they don't rely on the development of antibodies (which can take several weeks); however, these tests have limitations in that DNA testing cannot distinguish between dead and living organisms and the DNA amplification process needed for PCR may lead to a high rate of false-positive results. Furthermore, the bloodborne phase post a tick bite is usually brief and the concentration of spirochetes is very low. Current data indicates that PCR only detects *B. burgdorferi* DNA in the blood of less than 50% of patients in the early acute stage of the disease when the erythema migrans rash is present and by the time symptoms of Lyme disease have been present for a month or longer, spirochetes can often no longer be found in the blood.

While we are hopeful that the T2Lyme assay will have improved performance over these PCR-based assays given the T2MR's ability to detect the presence of organisms at a very low level of detection, we admit that direct detection from blood will be difficult given *B. burgdorferi* does not stay in the bloodstream for very long.

Management

John McDonough, CEO: Mr. McDonough has served as T2's President and Chief Executive Officer and a member of the Board of Directors since November 2007. From 2003 to 2007, he held various positions at Cytyc Corporation, a company engaged in the design, development, manufacturing and marketing of clinical products that focus on women's health, where he ultimately served as President of Cytyc Development Corporation.

Marc Jones, CFO: Mr. Jones has served as T2's Chief Financial Officer since April 2013. From January 2013 to March 2013, he was Chief Financial Officer of Crashlytics, a mobile device software company, until its acquisition by Twitter. From January 2012 to January 2013, Mr. Jones was Chief Financial Officer of Fluidnet, a medical device company. From June 2007 to August 2011, Mr. Jones was Chief Financial Officer of CHiL Semiconductor, a power management solutions company until its acquisition by International Rectifier.

Sarah Kalil, COO: Ms. Kalil has served as T2's Chief Operating Officer since August 2013. From August 2010 to August 2013, she was Chief Operating Officer of Interlace Medical, a medical device company, which was acquired by Hologic, Inc., a diagnostics company. From April 2009 to August 2010, Ms. Kalil was President and Chief Operating Officer of Boston Endo-Surgical Technologies, a medical device company. From 2002 to 2009, Ms. Kalil was Operations Director of Innovend, a medical molding company. Ms. Kalil is a member of the Executive Council of the Susan F. Smith Center for Women's Cancers at Dana Farber and on the board of the Pleiades Foundation.

Thomas Lowery, PhD, Chief Scientific Officer: Dr. Lowery, has served as T2's Chief Scientific Officer since September 2013. Since joining the company in

2007, he has held various technical leadership roles in the assay, methods, reagents and detector development programs. Prior to joining T2, Dr. Lowery conducted research at the University of California Berkeley focused on developing innovative magnetic resonance based biosensors for molecular imaging. Dr. Lowery received his Ph.D. in chemistry from the University of California, Berkeley and his B.S. in biochemistry from Brigham Young University.

Michael Pfaller, MD, Chief Medical Officer: Dr. Pfaller has served as T2's Chief Medical Officer since March 2014. From 2005 until he joined T2, Dr. Pfaller was a consultant to JMI Laboratories, managing the in vitro testing of fungal and bacterial isolates. From 1983 to 2005, he was Clinical Director of Clinical Microbiology Laboratory at the University of Iowa, as well as Interim Director of Clinical Laboratories from 1984 to 1985. He currently serves as Co-Editor in Chief of the American Society for Microbiology Manual of Clinical Microbiology, 11th edition and as co-editor of the 8th edition of Medical Microbiology. Dr. Pfaller received his M.D. from the Washington University School of Medicine and his B.A. in chemistry from Linfield College.

Competition

We believe T2 competes in the same segment of the market as blood culture, but as a complementary tool. T2's panels cannot replace blood cultures, as the growth of a detected organism (starts within a blood culture bottle) is required in order to determine its susceptibility/resistance profile. We believe T2's main advantage vs. other technologies is its ability to be used prior to a positive blood culture and the T2MR's limit of detection, which was shown to be as low as 1 CFU/mL in the company's pivotal *Candida* trial.

PCR-based diagnostics require the extraction of target cells from a patient sample. During this step, large quantities of cells are often lost. Then, when PCR is used to amplify the target signal, the reduced quantity of remaining cells typically results in limits of detection in the 100 – 1,000 CFU/ml range. Though this limit of detection is superior to blood culture bottles, it is inferior to T2's technology.

With that said, there are a number of technologies in development or in the early stages of commercialization both pre- and post-positive blood culture that could alter the current competitive landscape. Though T2 appears to be the furthest along among companies targeting the detection and identification of pathogens prior to positive culture (within 5-6 hours of a blood draw), we believe the evolution of the competitive landscape post-positive culture also matters. For example, some clinicians may see less value in adopting T2's platform that can identify *Candida* and/or bacterial pathogens within 5-6 hours of blood draw if they could have identification, susceptibility, and resistance information within ~14-16 hours of a blood draw (~8 hours for blood culture to turn positive + 1 hour for identification + 4-5 hours for susceptibility/resistance profiling). Given we already discussed the current competitive landscape (from blood culture to susceptibility/resistance testing) above, in this section we focus more various emerging technologies we came across for each stage of the diagnostic process.

Blood Culture/Prior to Positive Blood Culture (within ~8-12 hours of a blood draw):

As discussed above, the most commonly used blood culture systems today are sold by bioMerieux (the BacT/ALERT), BDX (the BACTEC), and TMO (the VersaTREK). We believe T2 is the only company with an FDA-approved diagnostic product that can identify pathogens associated with bloodstream infections directly from a blood sample and at limits of detection as low as 1 CFU/mL. However, there are a few companies with assays approved outside the U.S. or that have assays in development.

Abbott: As discussed above, Abbott's IRIDICA System, which is CE marked as of December 2014 but not FDA approved, is also expected to identify pathogens direct from blood prior to positive blood culture. Per our diligence, the company offers/plans to offer several assays, across various sample types:

> BAC BSI (sample type: EDT whole blood) and BAC SFT (sterile fluids and tissues) that will cover 750+ bacteria, *Candida*, and 4 antibiotic resistance markers, mecA, vanA, vanB, and kpc.
>
> BAC LRT (BAL and ETA) that will cover 750+ bacteria, *Candida*, and 4 antibiotic resistance markers, mecA, vanA, vanB, and kp with additional semi-quantitative threshold.
>
> Fungal (BAL and Isolates) that will cover 200+ fungi.
>
> Viral IC (Plasma) that will cover 130+ viruses in 13 reporting groups.

The IRIDICA platform uses a combination of Polymerase Chain Reaction and Electrospray Ionization Mass Spectrometry (PCR/ESI–MS). Based on a 2014 article we came across, it seems the system is designed to fit on a bench top, can process up to six samples at a time, and requires 5 ml of whole blood. Other sample types, such as plasma, sputum, bronchial lavage or tissue can also be used on the system. As of mid-2014, the sample prep time required for IRIDICA (an estimated 30 minutes of laboratory technician hands-on-time) was still a rate-limiting step in the technology's overall workflow as very small amounts of pathogen DNA must be isolated from a background of human DNA in order for the amplification to lead to a detectable sample. Additionally, as if mid-2014, identification results could be provided in ~6-8 hours, which would compare to ~3-5 hours with T2's platform.

Also in 2014, data from ABT's RADICAL study, a multicenter observational study comparing results from direct blood specimen testing using PCR/ESI-MS to standard microbiology in critically-ill patients were released. Eight ICUs across six European countries participated in the study and a total of 609 direct blood specimens from 543 patients were tested. Culture/PCR comparisons were as follows: +/+ 54; +/- 13; -/ + 169; and -/- 393, respectively, for a sensitivity of 81%, specificity of 69%, PPV of 24% and NPV of 97%. The analysis of additional sample types corroborated direct blood findings in 58% of cases where multiple specimens from the same patients were analyzed. Results from the study were then reviewed by an independent expert panel of physicians who concluded that a different course of care would have been considered in 57% of cases where PCR/ESI-MS was positive and 41% of these changes would have resulted in altered, instituted, or ceased antibiotic therapy earlier.

As of ABT's 1Q earnings call, the company was "early into the launch of our IRIDICA". To our knowledge, the company has not yet communicated plans to seek FDA approval at this time.

Many of the following technologies/assays seem very early in development. We plan to do more work when additional data is available.

Analytik Jena: The VYOO assay utilizes a multiplex PCR method for the detection of 46 sepsis-related pathogens and resistance genes (34 bacterial species, 7 fungal species and 5 resistance genes). Per the company's website the analytical sensitivity of the VYOO test (based on spiked whole blood) is estimated at 5-100 CFU/mL depending on the target with results available in ~7 hours. However, some published literature we came across indicates that the assay's sensitivity is quite low, ranging from 38-60%.

Biocartis (BCART, Not Rated): Biocartis is a commercial-stage molecular diagnostics company that is developing and marketing a test menu that addresses unmet clinical needs in oncology and infectious diseases. The company went public in April 2015; shares currently trade on the Euronext Brussels under the ticker BCART. Biocartis' Idylla platform can be used with a variety of primary clinical sample types, including blood, plasma, serum, urine, sputum, stool, swab, FFPE, and fine needle aspirates and can detect multiple biomarkers (up to 30 targets in standard mode) per sample. Per the company's website, the platform's functionality stems from the complete integration of all process steps: sample liquefaction and cell lysis, DNA/RNA extraction, real-time PCR amplification and detection, and data analysis and reporting. Within infectious diseases, the company is initially focused on bringing an Ebola assay to market, followed by Influenza virus panels and then sepsis assays in 2017. The company expects its platform to be able to detect over 15 of the most common sepsis pathogens in ~30 minutes (without the requirement of a positive blood culture).

Molzym: The SepsiTest assay is based on Real-Time PCR detection and sequence identification of organisms causing sepsis. The SepsiTest is CE-IVD marked, but not available in the U.S. Per the company's website, within four hours the assay can provide information as to whether there is a bacteraemia and/or fungaemia. Then, in positive cases, sequencing can be performed to identify the species present. Current data on sensitivity and specificity varies from 37.5% – 87% and 85.8% – 100%, respectively.

Roche (RHHBY, Not Rated): Roche's SeptiFast Test is a multiplex real-time PCR assay, designed for use with the LightCycler 2.0 Instrument. The test combines rapid amplification with highly specific melting point analysis for rapid species identification of pathogens causing nosocomial blood stream infections within six hours. Per the company's website, SeptiFast can detect bacteria and fungi direct from a 1.5ml whole blood sample without prior incubation. Additionally, when samples test positive for *S. aureus* with SeptiFast, the MecA Test MGRADE, which tests for the presence of the mecA gene, can be run on the same instrument. The SeptiFast is not available in the U.S. at this time and current data suggests that the test's sensitivity ranges from 15-98%, depending on the group of patients tested. Additionally, we note that per Roche's website the SeptiFast test can detect at a concentration of

300 CFU/mL or less, which would compare to T2's T2MR detecting at 1-3 CFU/mL per the pivotal *Candida* trial.

Seegene: Seegene's Magicplex Sepsis Real-time Test (CE marked, but not FDA approved) screens whole blood samples for more than 90 pathogens that are thought to cause sepsis and tests for methicillin and vancomycin resistance within three hours (excluding extraction time). Furthermore, the test has the ability to identify 27 pathogens detected during screening within 30 minutes after the initial screening step. Per the testing method described on the company's website (utilizes conventional and real-time PCR), and a poster we came across we are unsure whether this assay has high enough sensitivity to be adopted prior to positive blood culture.

Specific Technologies: Specific Technologies is working on a blood culture system that can determine bacterial species and strain in the bottle during blood culture. Specific Technologies' SpecID combines incubation, detection, and identification into a single fully automated step within the timeline it typically takes for a standard blood culture bottle to turn positive. The company believes that the system can deliver detection information over 30% sooner than conventional blood culture systems and that organism identification can be made faster than the time it takes for conventional blood culture systems to detect a positive.

Rapid Identification Post-Positive Blood Culture and (some) Rapid Susceptibility/Resistance Information (~2-12 hours post positive blood culture)

Accelerate Diagnostics (AXDX, Neutral): Please see our AXDX initiation for information on how the company's ID/AST system works.

AdvanDx (OPGN, Not Rated): Last week, OpGen (OPGN) announced the acquisition of AdvanDx, "a healthcare solutions company driven to ensure early, appropriate antibiotic therapy for patients with bloodstream infections". In 2014, AdvanDx had gross revenue of ~$5M. AdvanDx's technology utilizes a Whole Cell Analysis (WCA) approach to pathogen identification using Peptide Nucleic Acid Fluorescence In Situ Hybridization (PNA FISH). Rather than utilizing one or two broad multiplex panels, each of AdvanDx's assays test for specific types of organisms. The QuickFISH for *Staphylococcus* identifies and differentiates *S. aureus* and *Coagulase-Negative Staph (CoNS); Enterococcus* identifies *E. faecalis*, E. *faecium* and other Enterococci; Gram-Negative identifies and differentiates between Gram-negative species of bacteria; and *Candida* identifies and differentiates Candida species, all within ~20 minutes of positive blood culture. To date, all QuickFISH assays, except for *Candida* are approved for use in the U.S. and all four assays have obtained CE mark.

Additional relevant tests made by AdvanDx include:

The mecA XpressFISH, which detects the active mecA gene from positive *Staphylococcus aureus* blood cultures in approximately one hour.

The *S. aureus*/CNS PNA FISH, which provides rapid identification of *S. aureus* and *Coagulase-Negative Staphylococci (CNS*) directly from GPCC-positive blood cultures in 90 minutes.

The *E. faecalis*/OE PNA FISH, which provides rapid identification of *E. faecalis*, *E. faecium* and other enterococci, directly from GPCPC-positive blood cultures in 90 minutes.

The *E. coli/P. aeruginosa* PNA FISH, which provides rapid identification of *E. coli* and *P. aeruginosa* directly from Gram-negative blood cultures in 90 minutes.

The GNR Traffic Light PNA FISH, which provides rapid identification of *E. coli*, *K. pneumoniae* and *P. aeruginosa* directly from Gram-negative blood cultures in 90 minutes.

The *C. albicans*/*C. glabrata* PNA FISH test, which provides the rapid identification of *C. albicans* vs. *C. glabrata*.

And, the Yeast Traffic Light PNA FISH, which provides rapid identification of up to five *Candida* species including *C. albicans* and/or *C. parapsilosis*, *C. tropicalis* and *C. glabrata* and/or *C. krusei* directly from yeast-positive blood cultures in 90 minutes.

In addition to its acquisition of AdvanDx, OpGen recently signed a five-year agreement with Fluidigm (FLDM, BTIG Not Rated) to develop tests for the identification, screening, and surveillance of multi-drug resistant pathogens that can be run on Fluidigm's Juno, which utilizes automating SNP genotyping assays and real-time endpoint PCR. OpGen's current tests include 1) the Acuitas MDRO Gene Test, which identifies the presence of antibiotic resistant genes directly from a single patient swab or clinical isolate and determines patients that are at risk for MDROs; 2) the Acuitas CR Elite Test which screens for antibiotic resistance genes and confirms the presence of *Carbapenem Resistant Enterobacteriaceae (CRE)* from a swab or an isolate; 3) the OpGen *C. difficile* DNA Complete Test which is a qualitative, real time PCR test that detects *C. difficile* genes from stool samples; and 4) The OpGen MRSA DNA Screening Test, which is a qualitative, real time PCR test that targets the mecA gene and detects *Methicillin resistant Staphylococcus aureus (MRSA)* from nasal swabs. The company's Acuitas Resistome Test, which genotypes MDRO culture isolates and genetically characterizes drug susceptibility and resistance phenotypes by the detection of more than 49 MDRO gene families, is currently in development.

BacterioScan: BacterioScan's 216Dx UTI Detection System is used to "rapidly detect bacterial infections at detection thresholds lower than existing methods, providing hospitals with the ability to identify potential UTIs before they reach a point which could add complexity to other care paths". Beyond the 216Dx System, BacterioScan is developing an Antibiotic Susceptibility Testing (AST) platform (model 3100Dx). This technology should allow clinicians to more efficiently determine mean inhibitory concentrations (MIC) for new and existing antibiotics and has potential future applications in industrial hygiene, water quality and safety testing. Per the company's website, the 3100Dx will be available in early 2016.

bioMerieux's FilmArray Multiplex PCR System: Currently in use; discussed above.

bioMerieux's VITEK MS MALDI-TOF System: Currently in use; discussed above.

Bruker's Biotyper MALDI-TOF System: Currently in use; discussed above.

Cepheid (CPHD, Neutral, Analyst: Dane Leone): While CPHD's Xpert platform has some assays approved for healthcare-associated infections, including the Xpert MRSA/SA BC (detects MRSA and SA from positive blood culture specimens in approximately an hour), it does not appear the company is planning to launch a broad panel to identify other bacterial organisms from positive blood culture in the next several years.

GeneWEAVE: Utilizing its Smarticles technology (in development) GeneWEAVE is developing a fully automated, random-access system that can rapidly detect multi drug-resistant organisms (MDROs) and assess antibiotic susceptibility direct from clinical sample. Per the company, Smarticles are DNA-delivery bio-particles combined with GeneWEAVE-designed DNA molecules that cause live bacteria to produce light. These Smarticles are engineered to specifically target a species, genus, or family of bacteria, bind to the target and deliver a DNA molecule designed by GeneWeave that causes the bacteria to express luciferase (a molecule that produces light). If the bacteria are susceptible to a specific antibiotics or antibiotics, the organism (targeted by the Smarticles) will remain dark, whereas bacteria that are resistant to the antibiotic(s) will produce light. GeneWEAVE believes these results should be obtained direct-from-patient sample (nasal swab, rectal swab, urine, positive blood culture, wound) in four hours or less. Though this company still seems several years from market, early data (some of which was presented at ASM in May this year) looks promising.

GenMark (GNMK, Buy, $15 PT, Analyst: Dane Leone) Diagnostics' ePLEX: GNMK is an early commercialization-stage molecular diagnostics company that differentiates itself through a unique electro chemical detection platform. As of the end of 1Q15, the company's installed base of XT-8 analyzers was 562. The company's next-generation ePlex (to be launched in Europe in 4Q15 and submitted to FDA in 1Q16 per company estimates) is expected to process a sample and provide an answer in under 90 minutes vs. multiple hours with the XT-8 platform. The company has several comprehensive multiplex panels in development, including: a respiratory pathogen panel (RP, viral and bacterial targets from nasopharyngeal swabs); a gram-positive panel (BCID-GP, bacterial and resistance targets from positive blood culture); a gram-negative panel (BCID-GN, bacterial and resistance targets from positive blood culture), a gastrointestinal pathogen panel (GI; bacterial, viral, and parasitic targets from stool samples); a central nervous system panel (CNS; bacterial, viral, and fungal targets from cerebrospinal fluid samples); and a fungal pathogen panel (FP; fungal targets associated with bloodstream infections from positive blood culture).

Hain Lifescience: Hain Lifescience's GenoType BC grampositive and GenoType BC gramnegative assays identify pathogens post-positive blood culture. The GenoType BC grampositive detects 17 different Gram-positive bacterial species and the presence of methicillin or vancomycin resistance, while the GenoType BC gramnegative detects 15 different Gram-negative bacterial species. Sub-culture is not required and the species differentiation and resistance determination is available within a few hours. Current sensitivity and specificity data for the assays are generally sparse, though we

did come across a few evaluations of the technology that had rates of identification ranging from 70-99%.

Miacom Diagnostics: Miacom Diagnostics' hemoFISH gram +, gram –, and Masterpanel are designed to identify/differentiate various species of gram + bacteria, gram – bacteria, or both within 30 minutes of positive blood culture. The hemoFish *S. aureus*/CNS screen is designed to identify/differentiate between *Staphylococcus spp.*, *S. aureus*, and *coagulase-negative Staphylococci*. The data we found on the assays were favorable, with overall sensitivity and specificity rates of the hemoFISH tests above 90%.

Mobidiag: Mobidiag's Prove-it Sepsis Assay uses PCR and microarray detection to identify over 60 bacteria, the mecA methicillin resistance marker and 13 fungi in a single test with an estimated assay time of ~4 hours. Per published studies, data on sensitivity and specificity ranges between 64% - 95% and 96% - 99%, respectively. The assay has CE mark, but is not FDA approved.

Nanosphere's Verigene System: Currently in use; discussed above.

POCARED Diagnostics: POCARED Diagnostics' P-1000 (currently under development) "uses the unique physical properties of intrinsic fluorescence to provide a fully automated, direct specimen, CULTURE-FREE Microbiology and reagent- free solution for microorganism detection, identification and enumeration." In May 2015, the company announced that POCARED's P-1000 had successfully identified 5 antimicrobial resistance markers: KPC, NDM, vanB, mecA and OXA. We will do additional work on the company as more data become available.

Identification and Susceptibility/Resistance Information (~24-72 hours post-positive blood culture)

The most widely adopted automated ID/AST systems today include the Phoenix, VITEK 2, and MicroScan Systems. With each of these systems, the isolation of specific colonies or "isolates" and subsequent overnight culturing are typically required to produce enough organisms that can be tested. Given these steps, identification and susceptibility/resistance information is usually unavailable until ~24-72 hours post-positive blood culture.

Becton Dickinson's Phoenix System: Currently in use, discussed above.

Beckman Coulter's (DHR) MicroScan System: Currently in use; discussed above.

bioMerieux's VITEK 2 System: Currently in use; discussed above.

Thermo Fisher's Sensititre Instrumentation and ID/Susceptibility MIC Plates: Currently in use. TMO purchased Trek Diagnostic Systems and its ID/AST technology in 2011; at the time Trek had ~$30M in revenue. Currently there are several versions of the system available, some semi-automated and some fully-automated. The Sensititre identification plates can provide organism identification within ~5 hours for Gram-negative organisms and after overnight incubation for both Gram-negative and Gram-positive organisms. For AST, the Sensititre System utilizes 96-well microtiter plates that are

available in both standard and custom formats and contain doubling dilutions of antibacterial agents and specific substrates. Results can either be read manually by the visual reading of growth or via an automated technology that measures fluorescence to determine bacterial growth.

TTOO Income Statement	Dec-12	Dec-13	Mar-14	Jun-14	Sep-14	Dec-14	Dec-14	Mar-15	Jun-15	Sep-15	Dec-15	Dec-15	Mar-16	Jun-16	Sep-16	Dec-16	Dec-16	Dec-17	Dec-18
$ millions	FY12 A	FY13 A	1Q14 A	2Q14 A	3Q14 A	4Q14 A	FY14 A	1Q15 A	2Q15 E	3Q15 E	4Q15 E	FY15 E	1Q16 E	2Q16 E	3Q16 E	4Q16 E	FY16 E	FY17 E	FY18 E
Product Revenue	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.01	0.15	0.17	0.55	0.88	0.40	0.79	1.23	1.95	4.38	22.73	80.91
Research and Grant Revenue	0.02	0.27	0.00	0.00	0.00	0.12	0.12	0.18	0.00	0.00	0.00	0.18	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Total Revenue	**0.02**	**0.27**	**0.00**	**0.00**	**0.00**	**0.12**	**0.12**	**0.19**	**0.15**	**0.16**	**0.54**	**0.85**	**0.40**	**0.79**	**1.23**	**1.95**	**4.38**	**22.73**	**80.91**
y/y growth		*1300.0%*					*-55.3%*				*353.8%*	*617.2%*	*115.0%*	*424.8%*	*653.8%*	*261.8%*	*412.9%*	*419.3%*	*255.9%*
COGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.14	0.14	0.44	0.72	0.32	0.59	0.86	1.17	2.95	10.54	31.83
Gross Profit	0.02	0.27	0.00	0.00	0.00	0.12	0.12	0.19	0.01	0.02	0.10	0.13	0.08	0.20	0.37	0.78	1.43	12.19	49.08
R&D	11.73	14.94	5.07	4.70	4.80	5.21	19.78	5.87	6.00	6.20	6.40	24.47	6.60	6.80	7.00	7.20	27.60	30.80	37.00
SG&A	2.95	5.02	1.84	2.45	2.98	3.75	11.02	4.47	5.00	5.50	6.00	20.97	6.50	7.00	7.50	8.00	29.00	42.00	58.00
Total Operating Expenses	14.67	19.96	6.91	7.15	7.79	8.96	30.80	10.34	11.00	11.70	12.40	45.44	13.10	13.80	14.50	15.20	56.60	72.80	95.00
EBIT	**-14.65**	**-19.69**	**-6.91**	**-7.15**	**-7.79**	**-8.84**	**-30.68**	**-10.15**	**-10.99**	**-11.68**	**-12.30**	**-45.30**	**-13.02**	**-13.60**	**-14.13**	**-14.42**	**-55.17**	**-60.61**	**-45.92**
Other (expense) income	0.20	-0.92	-0.01	-0.15	-0.30	-0.24	-0.71	-0.47	-0.45	-0.45	-0.45	-1.82	-0.45	-0.45	-2.00	-2.00	-4.90	-8.00	-8.00
Pretax Income	-14.46	-20.61	-6.92	-7.30	-8.09	-9.08	-31.39	-10.62	-11.44	-12.13	-12.75	-47.12	-13.47	-14.05	-16.13	-16.42	-60.07	-68.61	-53.92
Income taxes (benefit)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net Income (loss)	**-14.46**	**-27.52**	**-8.83**	**-9.21**	**-8.85**	**-9.08**	**-35.96**	**-10.62**	**-11.44**	**-12.13**	**-12.75**	**-47.12**	**-13.47**	**-14.05**	**-16.13**	**-16.42**	**-60.07**	**-68.61**	**-53.92**
EPS		**-19.72**	**-6.25**		**-0.71**	**-0.45**	**-4.15**	**-0.53**	**-0.57**	**-0.60**	**-0.63**	**-2.34**	**-0.59**	**-0.61**	**-0.70**	**-0.71**	**-2.60**	**-2.66**	**-1.76**
Diluted Shares Outstanding		1.40	1.41		12.38	20.04	8.67	20.08	20.13	20.17	20.22	20.15	22.98	23.04	23.09	23.15	23.06	25.75	30.64
EBIT	-14.65	-19.69	-6.91	-7.15	-7.79	-8.84	-30.68	-10.15	-10.99	-11.68	-12.30	-45.30	-13.02	-13.60	-14.13	-14.42	-55.17	-60.61	-45.92
D&A	0.57	0.58	0.14	0.30	0.02	0.23	0.69	0.25	0.34	0.36	0.38	1.33	0.41	0.42	0.44	0.47	1.72	2.32	3.44
EBITDA	-14.08	-19.11	-6.76	-6.85	-7.77	-8.61	-29.99	-9.90	-10.65	-11.32	-11.92	-43.97	-12.61	-13.19	-13.69	-13.95	-53.45	-58.28	-42.49
Margins																			
Gross Profit	NM	NM	NM	NM	NM	NM	NM	NM	10.0%	15.0%	20.0%	15.7%	20.0%	25.0%	30.0%	40.0%	32.6%	53.6%	60.7%
EBIT	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-3220.6%	-1728.0%	-1146.6%	-738.1%	-1260.3%	-266.6%	-56.8%
EBITDA	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-3120.2%	-1675.2%	-1111.2%	-714.2%	-1221.0%	-256.4%	-52.5%
Pretax Income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-3331.9%	-1785.2%	-1308.9%	-840.4%	-1372.3%	-301.8%	-66.6%
Net Income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	MN	-3331.9%	-1785.2%	-1308.9%	-840.4%	-1372.3%	-301.8%	-66.6%
Expenses																			
COGS as a % of revenue	NM	NM	NM	NM	NM	NM	NM	NM	91.6%	87.1%	80.8%	84.3%	80.0%	75.0%	70.0%	60.0%	67.4%	46.4%	39.3%
SG&A as a % of revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	1607.9%	889.2%	608.6%	409.5%	662.5%	184.7%	71.7%
R&D as a % of revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	1632.7%	863.8%	568.0%	368.6%	630.5%	135.5%	45.7%
Total Operating Expenses	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	3240.6%	1753.0%	1176.6%	778.1%	1293.0%	320.2%	117.4%
Tax Expense (income)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net operating losses							**-84.80**	**-95.42**	**-106.86**	**-118.99**	**-131.73**	**-131.73**	**-145.20**	**-159.25**	**-175.38**	**-191.80**	**-191.80**	**-260.41**	**-314.33**

Source: BTIG Research estimates and company reports

TTOO Placement/Revenue Model	Mar-15	Jun-15	Sep-15	Dec-15	Dec-15	Mar-16	Jun-16	Sep-16	Dec-16	Dec-16	Mar-17	Jun-17	Sep-17	Dec-17	Dec-17
	1Q15 A	2Q15 E	3Q15 E	4Q15 E	FY15 E	1Q16 E	2Q16 E	3Q16 E	4Q16 E	FY16 E	1Q17 E	2Q17 E	3Q17 E	4Q17 E	FY17 E
United States:															
Capital Equipment															
T2 Instruments Placed	1	4	6	12	23	6	8	8	14	36	7	12	16	24	59
y/y growth						*500.0%*	*100.0%*	*33.3%*	*16.7%*	*56.5%*	*16.7%*	*50.0%*	*100.0%*	*71.4%*	*63.9%*
% penetration of target group of hospitals	0.2%	1.1%	2.4%	5.1%	5.1%	6.4%	8.2%	10.0%	13.1%	13.1%	14.7%	17.3%	20.9%	26.2%	26.2%
T2 Instruments Active	0	0	1	5	5	11	23	29	37	37	45	59	66	78	78
y/y growth								*2800.0%*	*640.0%*	*640.0%*	*309.1%*	*156.5%*	*127.6%*	*110.8%*	*110.8%*
seq. growth						*120.0%*	*109.1%*	*26.1%*	*27.6%*		*21.6%*	*31.1%*	*11.9%*	*18.2%*	
additions (assumes 6 month lag from contract)		0	1	4	5	6	12	6	8	32	8	14	7	12	41
% reagant rental	100%	80%	80%	80%	85%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
% sale	0%	20%	20%	20%	15%	20%	20%	20%	20%	20%	20%	20%	20%	20%	20%
# of instruments sold	0	1	1	3	5	1	1	2	4	8	0	2	2	5	9
ASP of instrument sold (000s)	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150
# of instruments being shipped/undergoing validation	1	5	10	18	18	18	14	16	22	22	21	19	28	40	40
Revenue from sale of instruments ($M)	**0.0**	**0.2**	**0.2**	**0.5**	**0.8**	**0.2**	**0.2**	**0.3**	**0.6**	**1.2**	**0.0**	**0.3**	**0.3**	**0.8**	**1.4**
Consumables															
Active Instruments	0	0	1	5	5	11	23	29	37	37	45	59	66	78	78
Tests/day/active system	0.2	0.4	0.6	0.8	0.5	1.0	1.2	1.4	1.6	1.3	1.8	3.0	4.0	5.0	3.5
Price/test	$250	$250	$250	$250	$250	$250	$250	$250	$250	$250	$250	$250	$250	$250	$250
Revenue Per Active System	$4,500	$9,000	$13,500	$18,000	$45,000	$22,500	$27,000	$31,500	$36,000	$117,000	$40,500	$67,500	$90,000	$112,500	$310,500
y/y growth						*400.0%*	*200.0%*	*133.3%*	*100.0%*	*160.0%*	*80.0%*	*150.0%*	*185.7%*	*212.5%*	*165.4%*
Est. Total U.S. Consumables Revenue ($M)	**0.0**	**0.0**	**0.0**	**0.1**	**0.1**	**0.2**	**0.6**	**0.9**	**1.3**	**3.1**	**1.8**	**4.0**	**5.9**	**8.8**	**20.5**
Total U.S. Revenue ($M)	**0.0**	**0.2**	**0.2**	**0.5**	**0.9**	**0.4**	**0.8**	**1.2**	**1.9**	**4.3**	**1.8**	**4.3**	**6.2**	**9.5**	**21.9**
Outside the U.S.															
Capital Equipment															
T2 Placements	1	0	0	1	2	0	0	1	1	2	3	5	5	8	21
y/y growth										*0.0%*	*NA*	*NA*	*400.0%*	*700.0%*	*950.0%*
T2 Instruments Active	1	1	1	1	1	1	2	2	2	2	3	4	7	12	12
y/y growth										*100.0%*	*200.0%*	*100.0%*	*250.0%*	*500.0%*	*500.0%*
seq. growth						*0.0%*	*100.0%*	*0.0%*	*0.0%*		*50.0%*	*33.3%*	*75.0%*	*71.4%*	
additions (assumes 6 month lag from contract signing)		0	0	0	0	0	1	0	0	1	1	1	3	5	10
% reagant rental	100%	50%	50%	50%	63%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
% sale	0%	50%	50%	50%	38%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
# of instruments sold	0	0	0	0	0	0	0	0	0	0	0	1	0	1	2
ASP of instrument sold (000s)	$120	$120	$120	$120	$120	$120	$120	$120	$120	$120	$120	$120	$120	$120	$120
# of instruments being shipped/undergoing validation	0	0	0	1	1	1	0	1	2	2	4	8	10	13	13
Revenue from sale of instruments ($M)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.1**	**0.0**	**0.1**	**0.2**
Consumables															
Active Instruments	1	1	1	1	1	1	2	2	2	2	3	4	7	12	12
Tests/day/active system	0.1	0.2	0.3	0.4	0.3	0.5	0.6	0.7	0.8	0.7	0.9	1.3	1.7	2.2	1.5
Price/test	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150	$150
Revenue Per Active System	$1,350	$2,700	$4,050	$5,400	$13,500	$6,750	$8,100	$9,450	$10,800	$35,100	$12,150	$17,550	$22,950	$29,700	$82,350
y/y growth						*400.0%*	*200.0%*	*133.3%*	*100.0%*	*160.0%*	*80.0%*	*116.7%*	*142.9%*	*175.0%*	*134.6%*
Est. Total OUS Consumables Revenue ($M)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.1**	**0.0**	**0.1**	**0.2**	**0.4**	**0.6**
Total OUS Revenue ($M)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.1**	**0.0**	**0.2**	**0.2**	**0.5**	**0.9**
Worldwide:															
Capital Equipment															
T2 Placements	2	4	6	13	25	6	8	9	15	38	10	17	21	32	80
y/y growth						200.0%	100.0%	50.0%	15.4%	52.0%	66.7%	112.5%	133.3%	113.3%	110.5%
T2 Instruments Active	1	1	2	6	6	12	25	31	39	39	48	63	73	90	90
y/y growth						1100.0%	2400.0%	1450.0%	550.0%	550.0%	300.0%	152.0%	135.5%	130.8%	130.8%
seq. growth		0.0%	100.0%	200.0%		100.0%	108.3%	24.0%	25.8%		23.1%	31.3%	15.9%	23.3%	
# of instruments being shipped/undergoing validation	1	5	10	19	19	19	14	17	24	24	25	27	38	53	53
Consumables Revenue Per Active System	$1,350	$2,700	$8,775	$15,900	$28,725	$21,188	$25,488	$30,077	$34,708	$111,461	$38,728	$64,329	$83,571	$101,460	$288,087
y/y growth															
WW Total Consumables Revenue (est.) ($M)	**0.0**	**0.0**	**0.0**	**0.1**	**0.1**	**0.3**	**0.6**	**0.9**	**1.4**	**3.2**	**1.9**	**4.1**	**6.1**	**9.1**	**21.1**
Total Product Revenue ($M)	**0.0**	**0.2**	**0.2**	**0.5**	**0.9**	**0.4**	**0.8**	**1.2**	**2.0**	**4.4**	**1.9**	**4.5**	**6.4**	**10.0**	**22.7**

Source: BTIG Research estimates and company reports

Appendix: Analyst Certification and Other Important Disclosures

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Risks
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