Q-linea anticipates accelerating ASTar® placements through 2025 and 2026 driving revenue growth

Q-linea AB (publ) (OMX: QLINEA) today shared a Company and Market update.

Key messages

- Anticipate total contracts for 30 – 40 ASTar instruments by end-2025; roughly 50% in US
- Additional placements of 60 – 90 instruments during 2026; US faster pace than EMEA
- Average yearly consumables revenue of 1.2 – 1.8 MSEK per ASTar; 2 – 3 months post-install
- Contract with US national reference laboratory signed March 2025; first installation during Q2 with potential of 4 – 8 placements in 2025 and 12-plus annually beyond
- US contracts typically with minimum volume expectation of 1,000 tests annually per ASTar
- Opex down 20% YTD 2025 with cash needs less than 15 MSEK per month through 2025
- Breakeven during 2027 as communicated previously

Short-term outlook

As outlined during our Year-End Report presentation, we aim to communicate consistent progress in three areas: Commercial, Clinical and Financial.

Commercial Outlook

Our goal is to increase ASTar contracts each quarter, with at least five expected in Q1 2025 (four already confirmed). Maintaining this trajectory, we anticipate 30+ ASTar instruments contracted by end-2025, supporting over 30,000 annual tests. Growth in 2026 will be driven by pipeline expansion, a more evenly distributed sales funnel, and adding ASTar units into existing contracts. We anticipate instrument placements should be at least double the 2025 level, or 60 – 90 units in 2026.

Regional processes are underway in Italy, the UK, and France, and large contracts may impact quarter-to-quarter predictability.

The US national reference lab network rollout will also influence ASTar placements. Since signing the MSA in March 2025, three pilot sites have been identified, with the first ASTar shipping in the coming weeks and timing for the other sites to be confirmed once local teams are organised. These pilots will focus on network integration (panel validation, LIS integration, and training) rather than technical evaluation which was completed in 2024. An S-curve rollout is expected with about six sites online during 2025, scaling to a dozen-plus annually over several years. This is a very preliminary assessment and will be determined by the customer's ultimate needs and preferences.

Our plan anticipates balanced ASTar demand across the US and EMEA in 2025 with the US accelerating further in 2026. US installations should exceed the 1,000 test per year ASTar 'fleet average' while EMEA may be lower due to smaller hospitals / labs and patient stratification.

Clinical outlook

In March, we will present new findings from the foundational LIFETIMES study in Italy, reinforcing ASTar's impact—over 30 hours faster than standard care—and its effects on length of stay and treatment economics which underpin the financial proposition for ASTar.
At ESCMID 2025 in Vienna, multiple podium and poster presentations will highlight LIFETIMES results alongside other European and US clinical studies collaborations with Q-linea, cementing the company's leadership and ASTar's value proposition.
The final US Early Access Programs conclude in H1 2025, with a packed schedule of conference presentations and journal publications throughout the year. 2025 will be a breakthrough year for Q-linea in the US, as clinical evidence from early adopters aligns with growing commercial momentum.

Financial outlook

Following the initial rights issue at approximately 91% subscription, the next milestone is the warrant component in May 2025. We hope to maintain the commitment of our shareholders and thereby secure an extended runway. In addition, we are exploring other avenues of non-dilutive funding, including grants, and are anticipating gross margin generation will increasingly contribute to cash needs quarter-on-quarter.
Revenue will come from both ASTar instrument sales and recurring revenues from the consumables (ASTar test kits), with test pricing between 1,200 – 1,800 SEK in the US and EMEA. Reagent-rental contracts will be priced at the higher end to offset instrument costs. Once fully operational (typically 2 – 3 months after shipping), each ASTar is expected to generate 1.2 – 1.8 MSEK in consumables revenue annually.
Our plan anticipates stable overall operational costs with continued shift from development activities to commercial and production activities.
At a macro level, we are closely observing the fast-evolving US tariff policies and have prepared mitigation strategies should the need arise.

US Market Development

Since FDA clearance in April 2024, we have built a commercial team of eight to establish Q-linea's ASTar platform as the gold standard in the emerging rapid AST space. Of the 4,000 – 5,000 microbiology labs in the US, we have identified the 1,200 – 1,600 that best fit the current ASTar proposition and have already engaged more than 250 of these labs, covering about 25% of US AST blood stream infection test volumes. The team continues to expand the pipeline with direct contacts and broad-market outreach.
Interest in rapid AST and ASTar is high. Competitive positioning is very strong, with the clear majority of those moving forward with rapid AST choosing ASTar over alternatives. Our short-term imperative is thus to focus on labs willing to move quickly towards implementation.
Revenue growth will be driven by: pipeline expansion (customer interactions), deal cycle time (months from contact to installation) and patient testing volumes per instrument.
The US pipeline includes 250+ engaged labs, with over 60 in active discussions for prospective evaluation of ASTar. Industry cycle times are typically 12–15 months, though some early adopters are moving faster, including the three contracts already signed in the US. Some labs will take more time to build their internal business case for adoption of what is a new technology for the industry.
Patient volumes vary by site, however we typically set a 'floor' of 1,000 tests per year in the US for contracted pricing. Labs with more than 4,000 tests annually may deploy a second ASTar for load balancing and redundancy, so an expected range of 1,000 – 2,500 tests annually is reasonable. These numbers could increase with future deployment of gram-positive and isolate testing.
We have one National Reference Lab Network contracted for ASTar deployment, two ASTars being installed

in the IDN segment (>50 hospitals 'in network') and multiple ongoing evaluations in the IDN and Large Independent segments, expected to convert to clinical installations in 2025 – 2026. IDNs represent the largest share of active discussions with concurrent evaluations increasing as the pipeline matures.
The US market has responded to ASTar faster than we expected. Securing a major reference lab contract just ten months post-FDA clearance is rare, as these labs typically adopt only proven technologies with established test volumes. This early adoption highlights ASTar's strong clinical and economic case, backed by published studies and exclusive NTAP funding from CMS. We look forward to early users sharing their experiences at industry conferences this year.
Overview of our three priority segments for ASTar in the US market:

National Reference Lab Networks	IDNs and Regional Reference Lab Networks	Large Independent Hospitals / Labs
200 – 500 addressable labs *	800 – 1,200 addressable labs	200 – 300 addressable labs
Five major players: LabCorp, Quest, Sonic, ARUP and Charles River	Top 20 IDNs have 40 – 200 hospitals. Many smaller IDNs serving US cities / regions	Mix of large academic hospitals and clinical care institutions that are independently-run
Each has 30 – 40 'core lab' locations with majority of volumes with smaller satellite locations for specialty testing or serving specific customers	Typically one or more 'hub lab' locations serving a hospital cluster with further satellite labs for specialty or near-to-patient testing.	Typically 500+ beds with their own microbiology lab and testing infrastructure.
Likely 1,500 – 5,000 tests per lab; volume driven by population catchment and local market share	Likely to deploy ASTar first in 'hubs' and later complement into satellites. Working assumption of one ASTar for 3 – 5 hospitals at full coverage.	May specialise in certain patient categories, some particularly relevant for ASTar, e.g., cancer, pediatric centres
* In addition to their 'core labs', LabCorp and Quest run hundreds of labs on behalf of customers as part of a 'managed lab services' model. These labs overlap with the other two customer segments	Regional Reference Lab Networks function similarly with multiple locations comprising a hub-and-spoke system	Likely to deploy 1 – 2 ASTars per customer with 1,500 – 2,500 tests /yr.
		Q-linea has partnered with several Academic hospitals for clinical studies, yielding publications and key opinion leader advocacy on behalf of rapid AST and ASTar.

Note: An integrated delivery network (IDN) is a large healthcare conglomerate that operates a network of healthcare facilities such as hospitals and clinics.

EMEA Market Development

The European market is characterised by a fragmented and heterogeneous customer landscape and in general moves slower than the US and the Middle East. Underlying clinical burden of AMR (antimicrobial resistance) varies significantly with low prevalence in Northern Europe and much higher AMR rates in Southern and Eastern Europe and Middle East.
Health care systems also vary significantly across the region, for example, Italy has a mix of regional tenders and direct purchases, France has more hospital buying groups and UK buying behaviour is driven by NHS policies at the regional and trust level. The Middle East is more approximate to the US model, with an added element of government policy influence which, in our case, encourages rapid AST adoption given the salience of AMR and Sepsis for the region.
In Italy, where we have a direct sales team and have concentrated our clinical study work, we have seen a clear impact with several regional projects and tenders ongoing, and a dozen-plus hospitals at various stages of discussion for ASTar. Belgium has also moved as a result of our clinical work with local key opinion leaders and we expect growth during this year. We expect that the UK will be the next major European market to move with shipments in 2025 and steady growth in 2026.
The Middle East shows great promise. Our partner, AMICO, has already lined up the first evaluations in the region which we expect to initiate in Q2 2025.

Company Operations and Cost Development

Last year was transformational for Q-linea, shifting from development to commercial expansion. We have streamlined from 127 to 94 employees and now have a team that is well-suited for delivering on our commercial, operational and product development aspirations.
We have reduced opex by 20% below 2024 year-to-date, and anticipate further cost savings throughout 2025, keeping cash needs below 15 MSEK per month. Team expansion in e.g., US commercial or operations, will depend on exceeding instrument placement and volume goals.
Ongoing efforts to lower the cost of goods will yield benefits this year. We are optimising consumables manufacturing, automating processes at key volume thresholds, and working with our instrument manufacturer, Sanmina, to improve planning, inventory, and commissioning. These efficiencies, along with scaling, will drive gross margin expansion through 2025 and 2026.

Message from CEO

Dear shareholders,
We appreciate your engagement and inquiries regarding our recent contracts in the US and Europe. While we cannot always disclose specifics, we want to provide clarity on our market position and ongoing developments.
Q-linea is entering its most exciting phase yet. ASTar is now in real-world patient testing, and during 2024, it likely helped save over 100 lives and prevented many more complications from sepsis. This impact is driving customer interest and reinforcing the case for adoption.
We are confident that 2025 will be the breakthrough year for rapid AST in the US, Europe, and the Middle East, with ASTar emerging as the clear segment leader.
Thank you for your continued support.

Best regards,
Stuart Gander, on behalf of the Q-linea team
President & CEO

For more information, please contact:

Stuart Gander, President & CEO, Q-linea
Stuart.Gander@qlinea.com
+1 857 409 7463

Christer Samuelsson, CFO /IR, Q-linea AB
Christer.Samuelsson@qlinea.com
+46 (0) 70-600 15 20

About Q-linea

Q-linea's rapid AST system, ASTar®, accelerates and simplifies the time-sensitive workflows faced during the treatment of patients with bloodstream infections and sepsis. Hospitals use ASTar to vastly reduce the time to optimal antimicrobial therapies and ensure that patients receive the correct treatments sooner — when time matters most. We are helping to create sustainable healthcare, now and in the future, and safeguard the effectiveness of antibiotics for generations to come.
Q-linea is headquartered in Uppsala, Sweden and has regional offices in Italy and the USA, with partnerships worldwide.
ASTar Instrument and ASTar BC G- Consumable kit are CE-IVD marked and FDA 510(k) cleared. For more information, please visit www.qlinea.com

This information is information that Q-linea is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-03-18 07:30 CET.

Attachments

Q-linea anticipates accelerating ASTar® placements through 2025 and 2026 driving revenue growth