



# IRRAS

Q4 2021  
Report  
16 February 2022



•  Hummingbird.  
ICP Monitoring

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# Q4 2021 Financial Highlights

**6** consecutive quarters of revenue growth



# Significant recent events

## CE Mark received for enhanced IRRAflow Drainage Catheter



- Enhanced catheter with improved kink resistance and drainage capabilities approved for use in European Union.

## ACTIVE clinical study initiated by Aarhus University Hospital



- Patient treatments begin with IRRAflow.
- Results will be captured in the ACTIVE clinical trial to prove IRRAflow's superiority vs. EVDs.

## First patients enrolled in ARCH clinical study



- ARCH compares use of IRRAflow with clot-busting medication vs. EVDs in IVH patients.
- Study will document ability & safety of using IRRAflow to deliver intracranial medication.

## Partnership with Lovell Government Services (LGS)



- IRRAS signed an agreement with LGS, to serve as its vendor for product orders and contract from US government facilities.

# Significant recent events after the quarter

## Largest IRRAf<sup>low</sup> dataset to date presented, confirming improved patient outcomes

Catheter Occlusion		0%*
Shunt dependence (IVH)		3/23 (13%)**
Vasospasm	Clinical	2/12 (17%)***
	Radiographic	3/12 (25%)***

- Surgeons from West Virginia University Hospital presented data from their first 45 IRRAf<sup>low</sup> patient treatments medical conference in VA.
- Data showed 0% occlusion rate and reduced incidence of infection, vasospasm, and shunt dependence compared to EVDs.

## First patients enrolled in ACTIVE clinical study



- Dr. Anders Korshøj from Aarhus University Hospital enrolled the first patient in the ACTIVE clinical study to evaluate the efficacy and safety of IRRAf<sup>low</sup> compared to traditional drainage systems.

## Expanded Intellectual Property Portfolio for IRRAf<sup>low</sup>



- Third patent issued for the IRRAf<sup>low</sup> system to provide coverage to administer therapeutic drugs using IRRAf<sup>low</sup>'s catheter.

# Key Financial Data

MSEK	Q4 2021	Q4 2020	2021	2020	2019	2018	2017
Revenue	7.2	2.5	22.4	7.4	5.3	6	12
Gross margin, %	Neg	Neg	Neg	Neg	Neg	Neg	Neg
EBIT	-43.5	-36.6	-136.5	-134.3	-151.5	-143.3	-61.5
Earnings per share (SEK)	-0.55	-0.57	-1.89	-2.46	-5.61	-5.83	-3.4
Cash flow from operating activities	-36	-28.7	-130.5	-133	-154	-97.4	-53.7
Liquid funds, end of period	55.9	135.6	55.9	135.6	85.1	158.1	244.2

# About IRRAS



IRRAS is a Swedish-American company focused on delivering innovative products for neurocritical care.

*IRRAS is listed on NASDAQ Stockholm*



### Direct Sales Presence

**United States**  
*San Diego, CA*

- Executive team
- Direct sales team
- R&D and Operations

**Sweden**  
*Stockholm*

- Legal HQ & Finance
- IR & IT

**Netherlands**  
• Global warehouse & Logistics

- United States
- Germany
- Sweden
- Netherlands



# Targeting Sizable Market Opportunity

**Intracranial Bleeding**  
**>\$1.8B<sup>6</sup> in EU & US**

**Hemorrhagic Stroke**

**8-10%**  
 CAGR<sup>1,2,3,4,5</sup>

**~200k** Surgically operated, EU & US<sup>2</sup>

**Chronic Subdural Hematoma**

**~500k** Surgically operated, EU & US<sup>4,5</sup>

**Traumatic Brain Injury**  
**\$600M in EU & US**

**5.4M** EU & US brain injuries each Year<sup>7</sup>

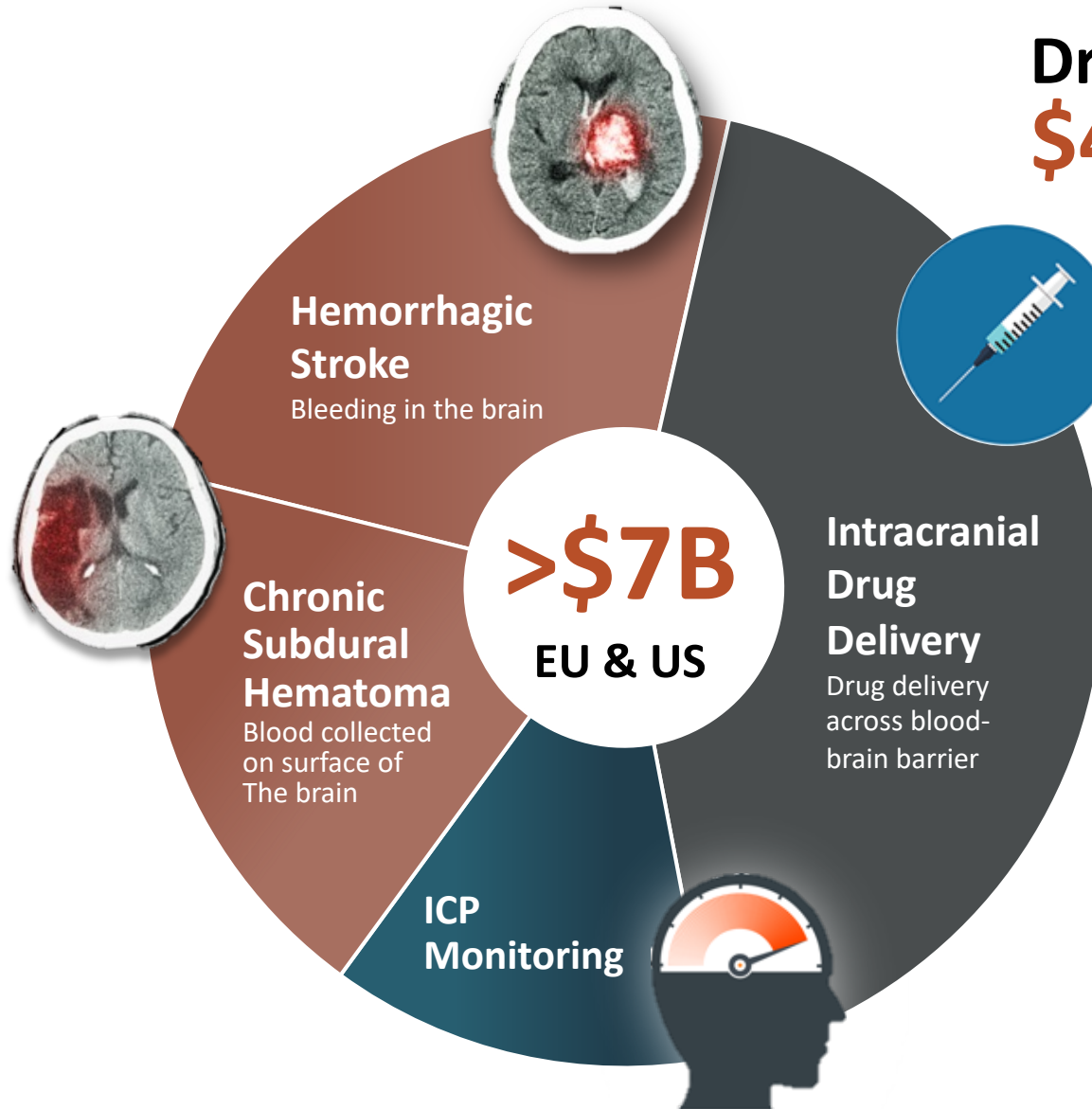
**6%**  
 CAGR<sup>7,5</sup>

**Drug Delivery**  
**\$4.6B**

**30%**  
 CAGR<sup>8</sup>

**~13% Epilepsy**  
**~17% Alzheimer's**  
**~20% Parkinson's**

First areas of focus are thrombolytic and antibiotic therapy



1. <http://www.strokecenter.org/patients/about-stroke/stroke-statistics/>  
 2. <https://www.nichd.nih.gov/health/topics/stroke/conditioninfo/risk>  
 3. Hatem A. Wafa, MPH, Charles D.A. Wolfe, MD, Eva Emmett, MPH, Gregory A. Roth, MD, Catherine O. Johnson, PhD, Yanzhong Wang, PhD. Thirty-Year Projections of Incidence, Prevalence, Deaths, and Disability-Adjusted Life Years. Stroke. 2020;51:2418–2427 10 Jul 2020. <https://doi.org/10.1161/STROKEAHA.120.029606>  
 4. Balsler, D., Farooq, S., Mehmood, T., Reyes, M., & Samadani, U. (2015). Actual and projected incidence rates for chronic subdural hematomas in United States Veterans Administration and civilian populations. *Journal of neurosurgery*, 123(5), 1209–1215. <https://doi.org/10.3171/2014.9.JNS141550>  
 5. Neuroscience Intensive Care Unit, Department of Neurosurgery, Mount Sinai School of Medicine, New York, NY, USA Report: National trend in prevalence, cost, and discharge disposition after subdural hematoma from 1998-2007  
 6. Estimates are based on total amount of hemorrhagic stroke and chronic subdural hematoma cases in the EU and US. Number of cases multiplied by an average charge of EUR 2,600 for IRRAS per set of disposables (one set of disposables required per case). Market potential excludes control unit.  
 7. Dewan, Michael & Rattani, Abbas & Gupta, Saksham & Batculon, Ronnie & Hung, Ya-Ching & Panchak, Maria & Agrawal, Amit & Adeleye, Amos Olufemi & Shrim, Mark & Rubiano Escobar, Andres & Rosenfeld, Jeffrey & Park, Kee. (2018). Estimating the global incidence of traumatic brain injury. *Journal of Neurosurgery*. 130. 1-18.  
 8. <https://www.grandviewresearch.com/press-release/global-drug-delivery-across-blood-brain-barrier-market>





# Comprehensive Portfolio in Neurocritical Care

## Intracranial Bleeding

## Traumatic Brain Injury



**The world's first irrigating intracranial drainage system!**

**The next generation of advanced neuromonitoring!**

Irrigation • Drainage • ICP Monitoring • One System

Most Accurate • Zero ICP Drift • Multimodal Monitoring





# System Components



**Automated Irrigation**



**Controlled Drainage**



**ICP Monitoring**



**IRRAflow Tube Set & Intelligent Digital Cassette**

**IRRAflow Dual-lumen Catheter**



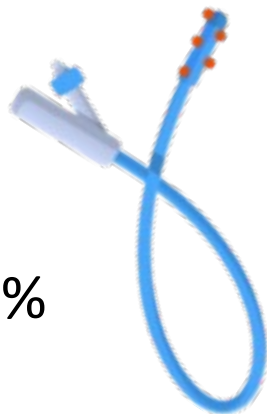
**IRRAflow Control Unit & Drainage Collection Bag**





In >300 patient treatments, **0%** catheter occlusion rate observed when system's irrigation is actively employed

Compared to documented literature showing up to 47% EVD occlusion rate<sup>1</sup>



Market-leading  
EVD



# Next-Gen IRRASflow Product Launch Underway

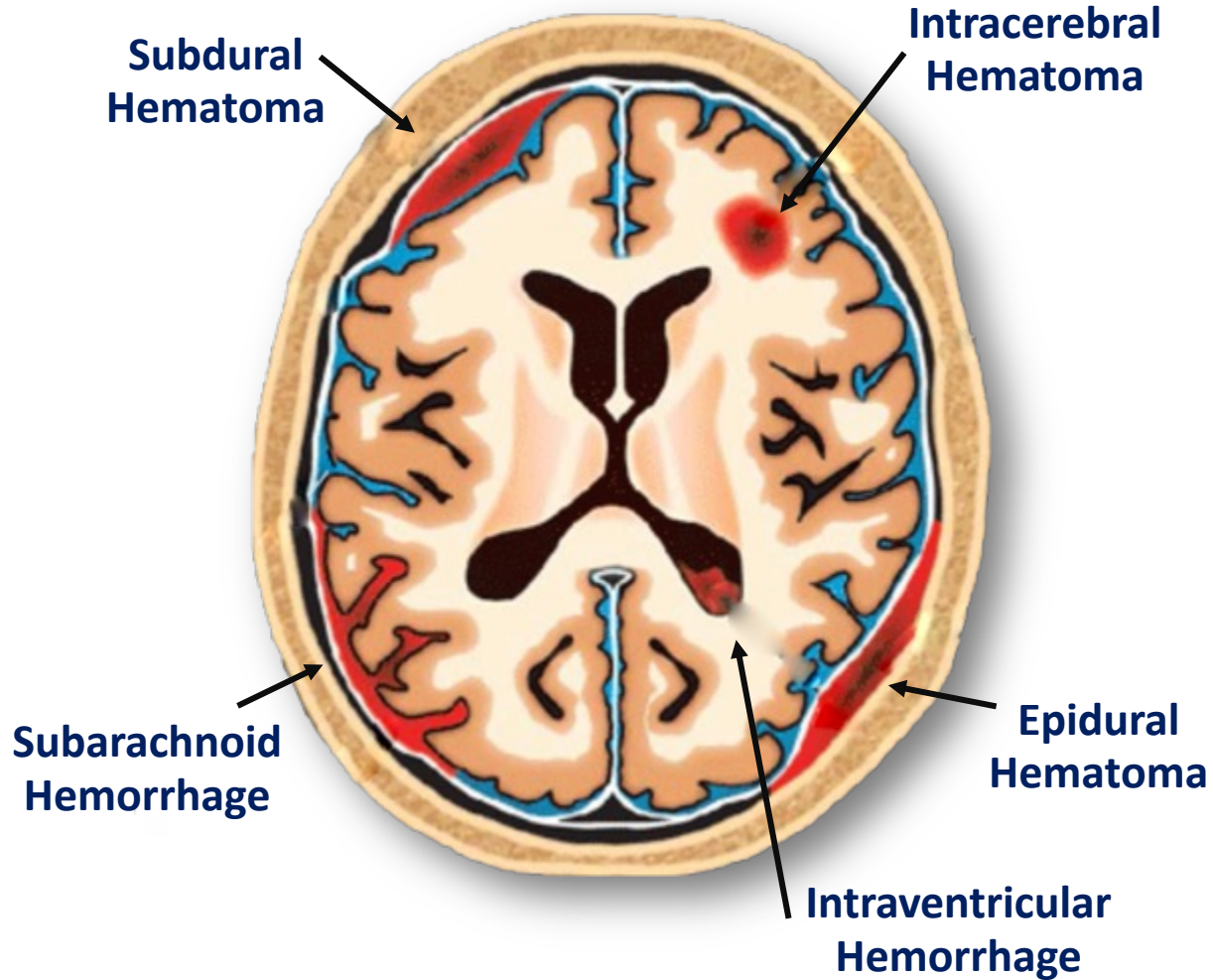


## Now commercially available in the US:

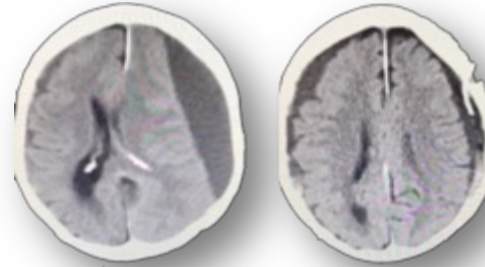
- ✓ Limited Market Release training has begun at first wave of accounts
- ✓ First commercial systems shipping this week



# IRRAflow Can Treat Multiple Disease States



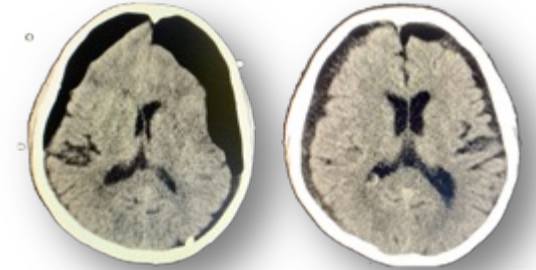
**Chronic Subdural Hematoma**



Pre-IRRAflow

Post-IRRAflow

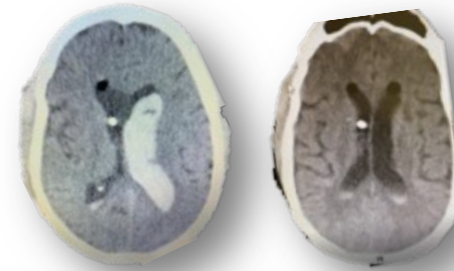
**Bilateral Chronic Subdural Hematoma**



Pre-IRRAflow

Post-IRRAflow

**Intraventricular Hemorrhage**



Pre-IRRAflow

Post-IRRAflow

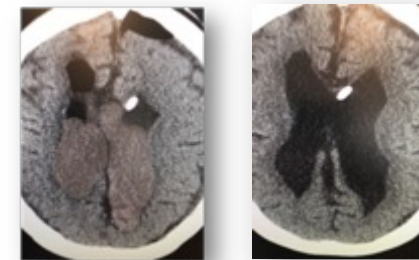
**Intraparenchymal Hemorrhage with Intraventricular Hemorrhage**



Pre-IRRAflow

Post-IRRAflow

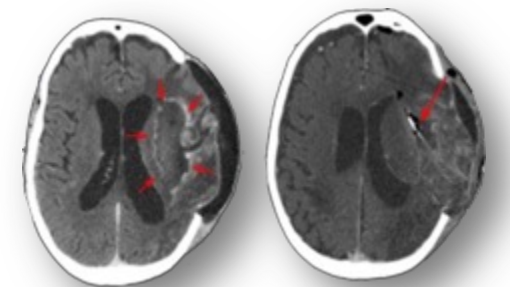
**Ventriculitis**



Pre-IRRAflow

Post-IRRAflow

**Cerebral Abscess**



Pre-IRRAflow

Post-IRRAflow

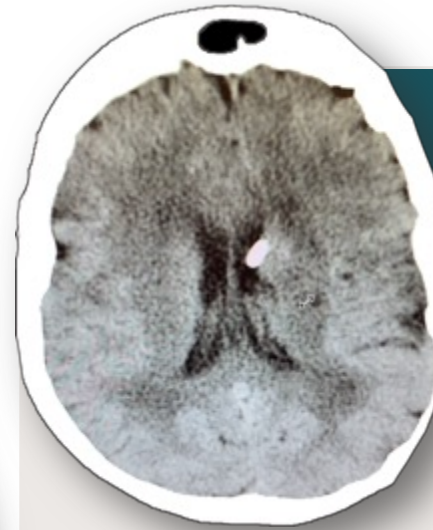
# Increasing Clinical Experience Continues to Document Superiority

## Treatment Description

- Female | 68 years old
- Patient arrived at Cottage Hospital in Santa Barbara, CA, with headache & nausea
- IRRAflow catheter inserted to the left lateral ventricle to evacuate blood from ventricular system
- Administered 4 mg of tPA in 1,000 mL saline with automated irrigation



Pre-IRRAflow  
Treatment



Post-IRRAflow  
Treatment

**36 hrs.**  
Treatment  
Time

## Treatment Results

- Head CT done prior to discharge showed noticeable improvement
- IRRAflow catheter irrigation was stopped after 36 hours
- After clamping, ICP remained stable <5mm Hg
- Patient exam improved with GCS of 14
- Catheter removed on day 3 post-placement

# Early Experience with Patient Treatment & Drug Delivery with **IRRAflow**<sup>®</sup>:

An Automatically Irrigating and Draining Ventricular Catheter

Presented by surgeons from **WVU Rockefeller Neuroscience Institute** at The Neurosurgical Society of the Virginias Annual Meeting

45

IRRAflow patient treatments



Post-IRRAflow

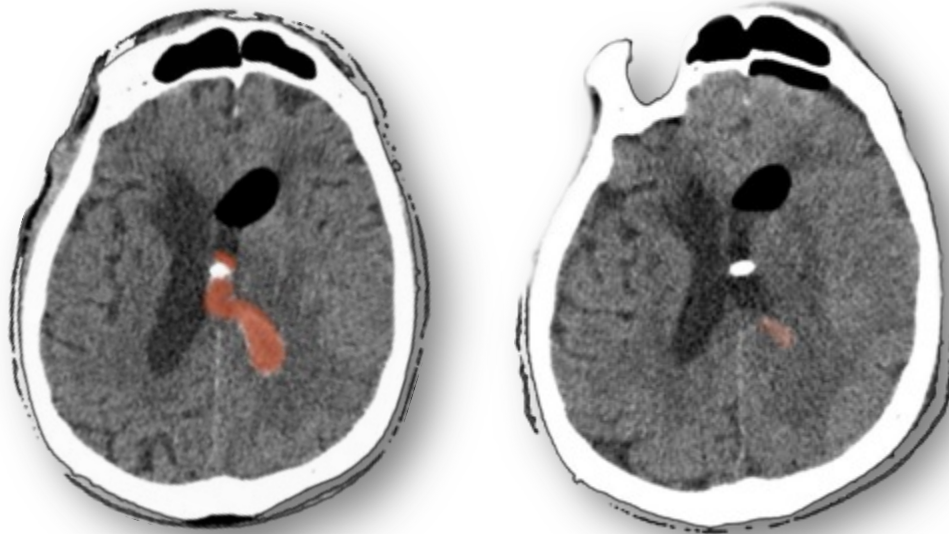
Complications	Ventriculitis	1 (2.2%)
	Mortality	9 (20%)
Intrathecal Medications administered	tPA	9 (20%)
	Vancomycin	2 (4.4%)
<b>Catheter Occlusion</b>		<b>0%*</b>
<b>Shunt dependence (IVH)</b>		<b>3/23 (13%)**</b>
<b>Vasospasm</b>	<b>Clinical</b>	<b>2/12 (17%)***</b>
	<b>Radiographic</b>	<b>3/12 (25%)***</b>
<b>SDH</b>	<b>MLS before: 4.9±2.6 MLS after 2d: 0.8± 1.2</b>	<b>Percentage improved 13/13 (100%)</b>

**\* Compared to 19% permanent, 41% temporary occlusion.**  
*Fargen et al. JNS 2016*

**\*\*Compared to 18% in literature. Clear III trial.**  
*Murthy et al. Neurology 2017.*

**\*\*\*Compared to 40-70% in literature.**  
*Bracard et al. Interventional Neuroradiology 2008*

# Patient Treatment from WVU Dataset Confirms IRRAflow Mechanism of Action



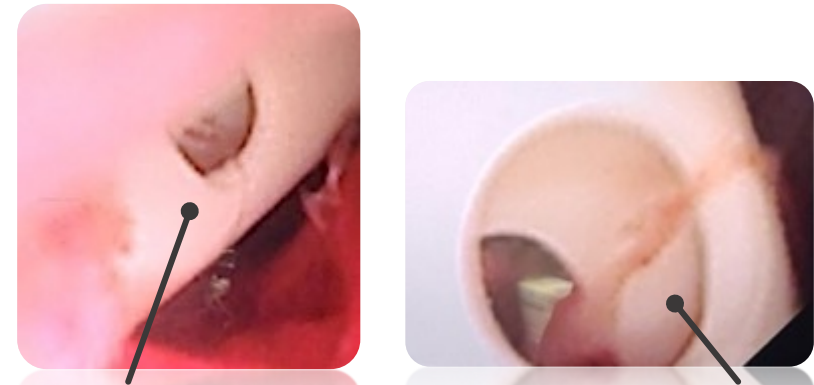
Pre-IRRAflow

Post-IRRAflow

- IRRAflow inserted directly in clot
- Irrigation performed with tPA
- Endoscopic evaluation performed on day 4 to remove persistent clot

Endoscopic images confirm impact of IRRAflow's automated irrigation

No occlusion formation even in heavy clot burden



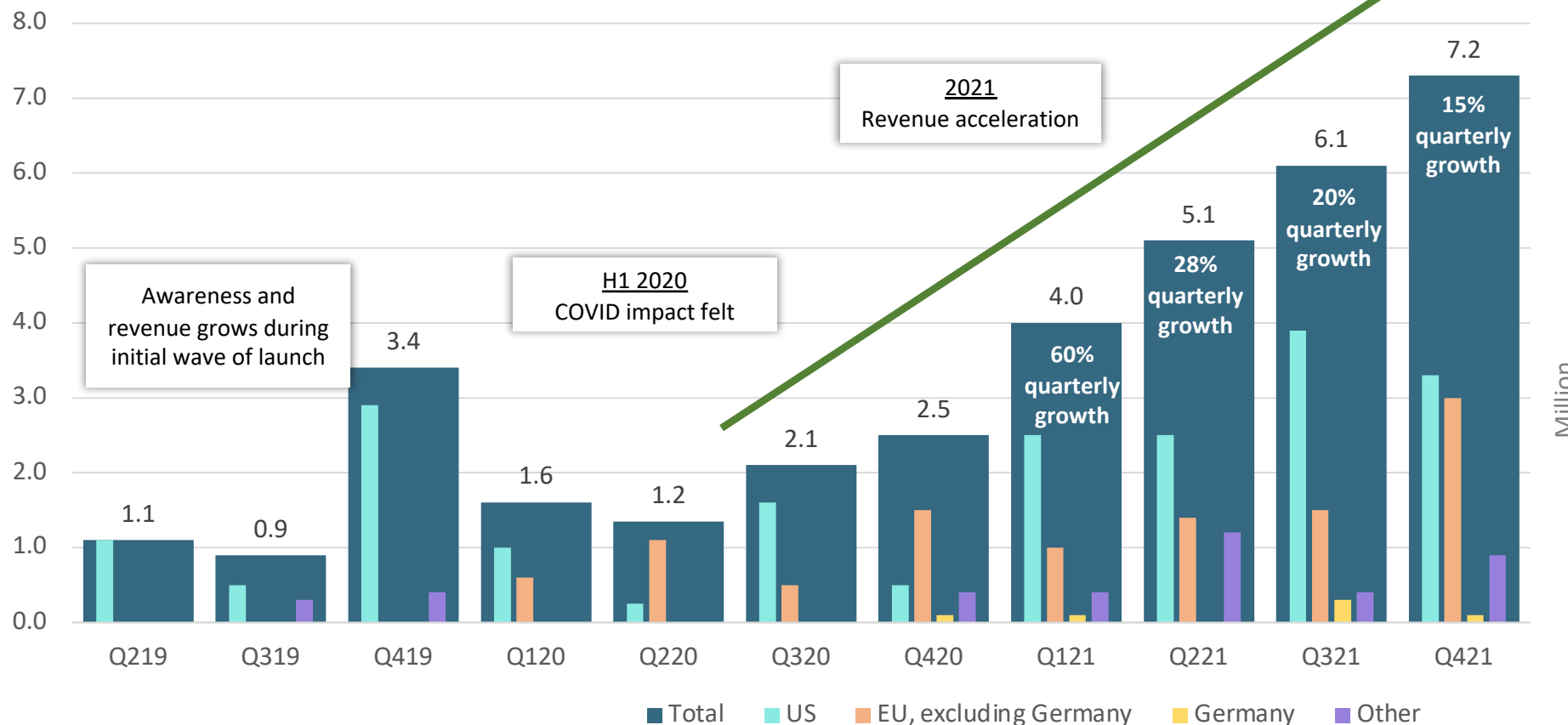
Irrigation cleansing the catheter holes, keeping the **catheter free of occlusions**

Images provided by Dr. Nicholas Brandmeir



# Consistently Demonstrated Revenue Growth

Global Revenue Per Quarter, MSEK



## Annual Revenue

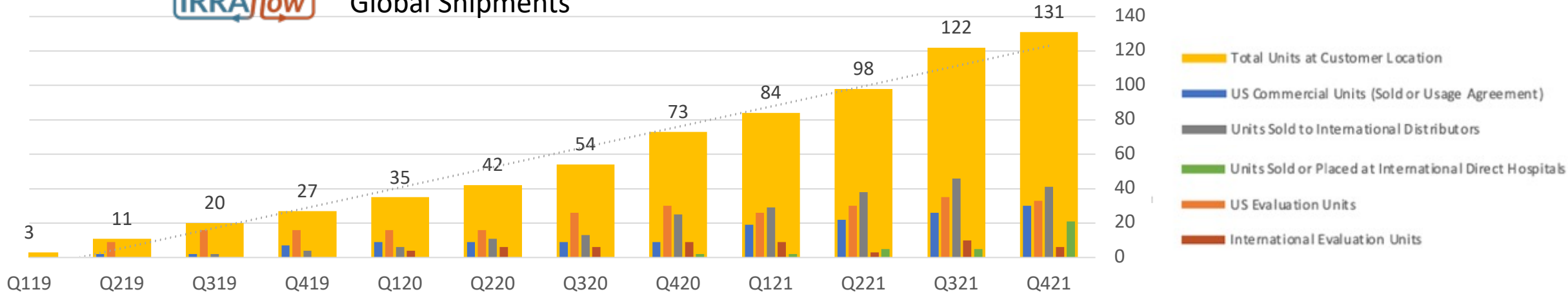
2019	2020	2021
MSEK 5.3	MSEK 7.4	<b>MSEK 22.4</b>
559K USD	841K USD	<b>2.61M USD</b>

# Metrics Confirm Growing Adoption

*Capital equipment footprint continues to expand*

## IRRAflow<sup>®</sup> Global Shipments

# of IRRAflow Systems



**131**

IRRAflow systems deployed globally

**7.4%** ▲  
QoQ Growth



**33**

Systems supporting US Evaluations

**-5%** ▼  
QoQ Growth



**30**

US Commercial systems driving disposable usage

**15%** ▲  
QoQ Growth



**16**

Systems with EU direct commercial customers

**6.6%** ▲  
QoQ Growth



**52**

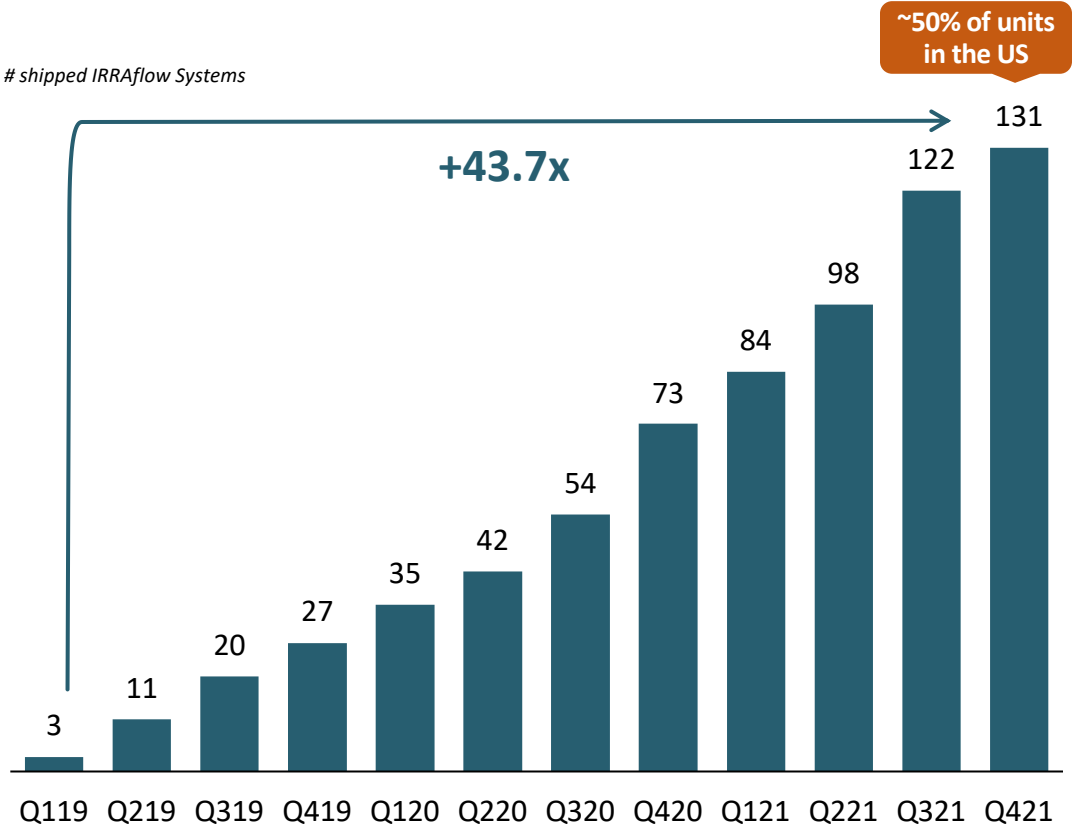
Systems sold to Distribution partners

**13%** ▲  
QoQ Growth



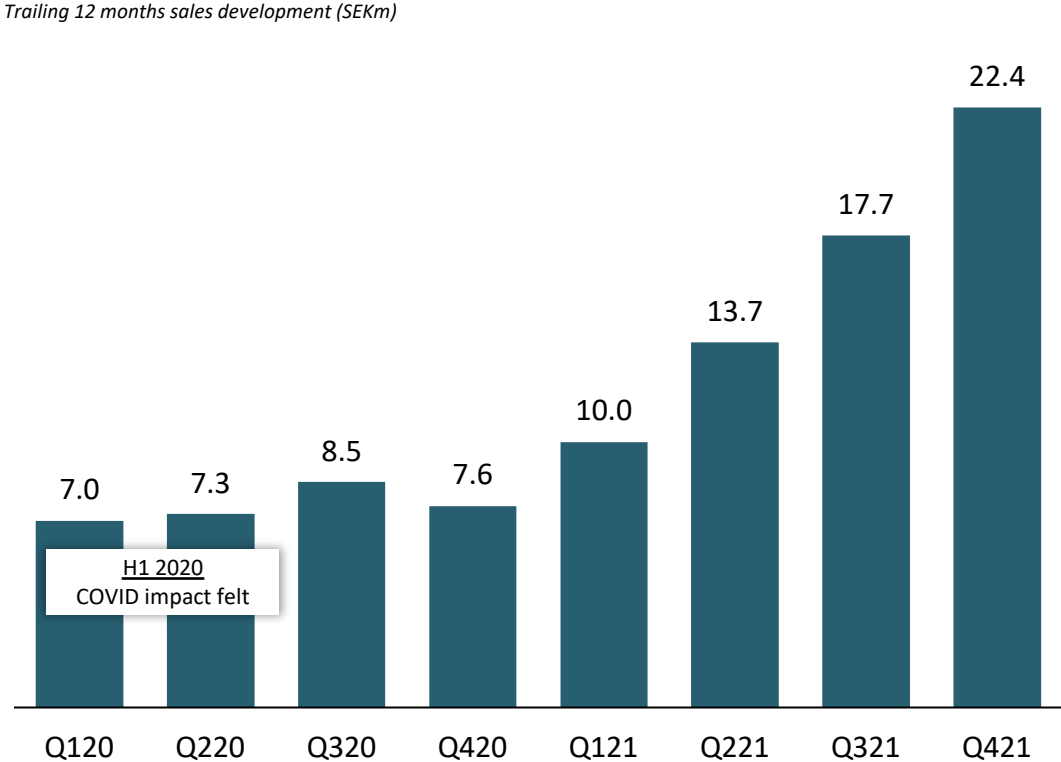
# Growing Install Base Increases Disposable Usage and Total Revenue

## Strong development in installed base...



**US commercial units and units sold to international distributors serve as main drivers in installed base**

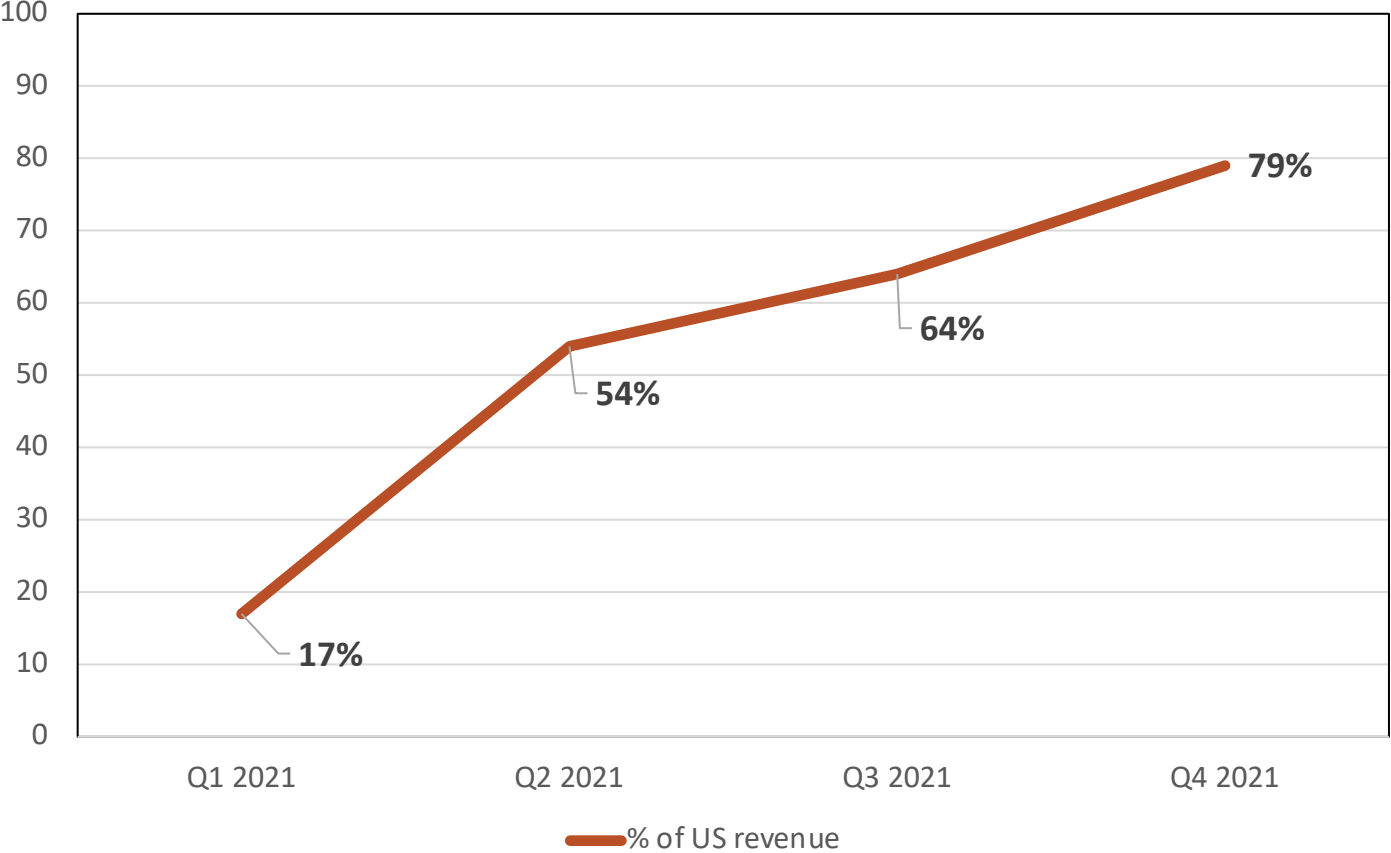
## ...driving sales growth



**Growth driven by disposable reorders and further expansion of distribution network**

# Increasing Adoption by Reference Sites Validates Business Model

US revenue growth driven by disposable reorders from commercial customers



**Adnan Siddiqui, MD**  
Secretary, SNIS  
CEO/CMO, The Jacobs Institute

- Working to replicate successful launches at Buffalo General and WVU



**Elad Levy, MD**  
President-Elect, CNS

- Growing adoption and resulting disposable reorders at US hospitals driving larger % of US revenue



**Nicholas Brandmeir, MD**  
Assistant Professor, WVU



# Q4 Commercial Highlights

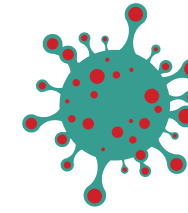
*Broad revenue contribution seen from a variety of sources*



Global distribution network expansion with initial orders from new partners in Baltic countries, Czech Republic, Bulgaria



Generated disposable order to support another new **IRRAflow** evaluation in Germany



Navigated through the COVID-19 omicron variant during Q4

**Watching future COVID hotspots, but business as usual resuming globally**



Received **IRRAflow** disposable stocking order from comprehensive stroke center, Vidant, new US commercial customer, in Greenville, NC



Disposable reorders from 5 US accounts and 3 international distributors

**1<sup>st</sup> patient treatments** with distributor partners



Generated disposable order to support new **IRRAflow** evaluation at Cottage Health, comprehensive stroke center in Santa Barbara, CA



West Virginia University Hospital continues to increase **IRRAflow** usage, including disposables and 3 additional control units



Croatia



Mexico

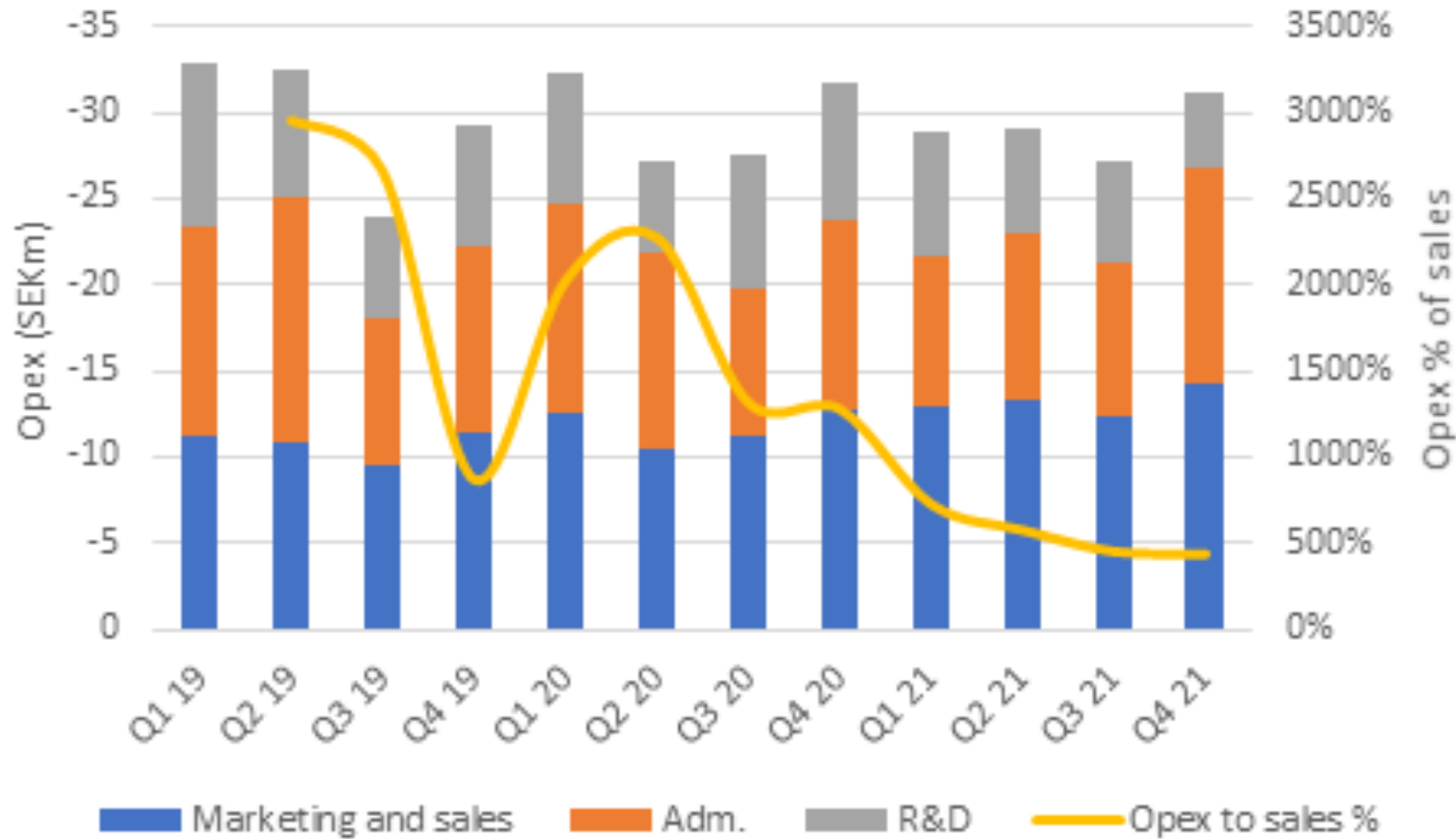


Lithuania



# Q4 Commercial Highlights

*Growth continues with focus on cost consciousness*



Administration currently includes Clinical, which will be shifted to R&D in future quarters

- Active Fluid Exchange with infused tPA significantly increases the removal of blood and reduces treatment time
- All cases demonstrated removal of 90% of blood in 72 hours
- All cases were completed in ~5 days
  - **Average of 14 days in ICU during CLEAR-III trial, which used tPA and traditional EVD**

# Active CSF exchange system is effective for IVH treatment

## Active Removal of Cerebral Haemorrhage

Behnam Reza Jahromi, Päivi Tanskanen, Felix Göhre, Johanna Pekkola, Jari Siironen

### INTRODUCTION

- Intracerebral haemorrhage (ICH) associated with intraventricular hematoma (IVH) has higher rates of morbidity and mortality.
- Removal of IVH depends on passive external ventricular drainage, which is time consuming and gives opportunity to IVH re-organize and have negative effect on neural tissue.

### OBJECTIVES

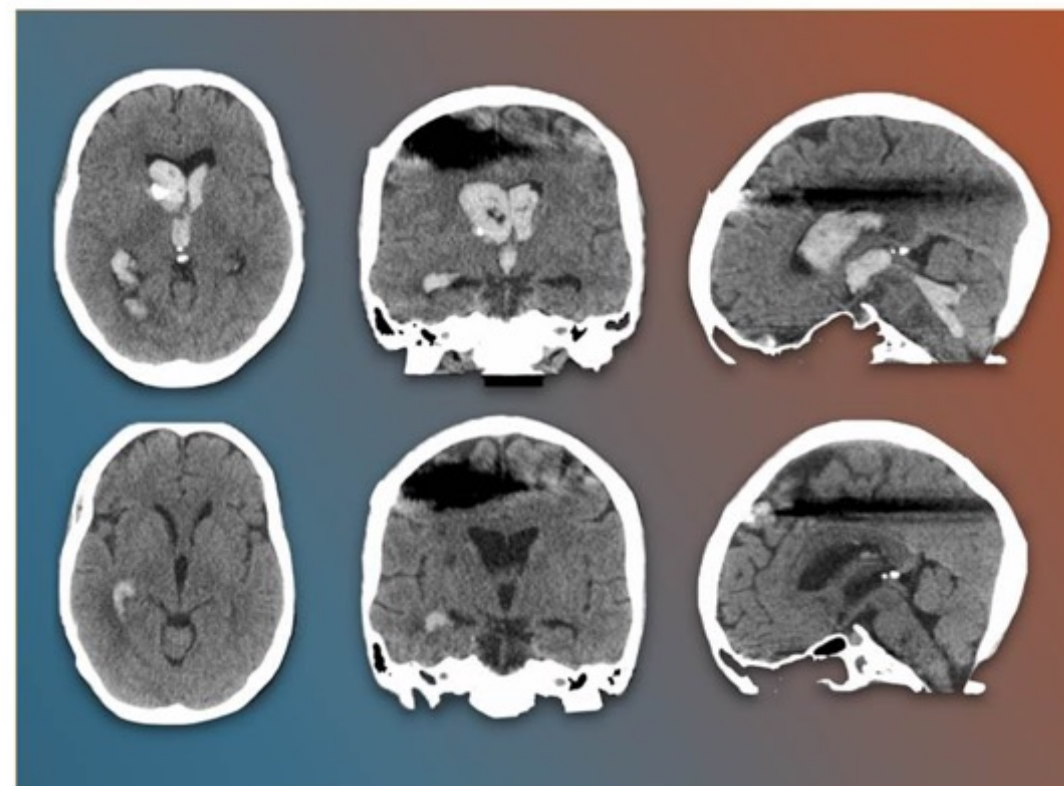
- Expedient removal of ICH and IVH should result in less organization of blood in the cerebrospinal fluid thus minimizing neural toxicity and facilitating better neurologic outcomes for patient and reduction in ICU time.
- We tested a novel fluid exchange system (active EVD) with controlled tPA infusion on 5 ICH and IVH cases to determine if rapid removal of blood could occur.

### METHODS

- In 2 cases, 2mg of tPA was administered manually over 2 consecutive days. In the other 3 cases, 2mg of tPA in 1,000 cc's of fluid was continuously infused over a period of 2 consecutive days.

### RESULTS

- In all 5 cases, CT demonstrated 90% removal of blood occurring in 72 hours or less.
- Further, in all cases, complete treatment with the device, from catheter insertion to removal, was completed in an average of 5 days.
- Figure 1 and 2 demonstrates removal of IVH in 47h with 2.4mg tpa.



### CONCLUSIONS

- Active removal of IVH with infusion of tPA and fluid exchange significantly increases the removal of blood and reduces treatment times compared to standard EVD treatment.
- Further, our case series substantiated a significant reduction in ICH.
- For this reason, we need future studies to assess the impact of tPA administration in ICH with active fluid exchange on neurological outcomes, ICU treatment time and need of standard EVD treatment

# Execute Clinical Projects to Document Superiority and Safety of Drug Delivery



Led by Helsinki University, Finland

60 Patients; Prospective randomized trial comparing IRRAflow versus standard EVD in treatment of IVH with infusion of tPA.

5 Patients Enrolled



Led by Aarhus University, Denmark

120 Patients; Prospective randomized trial comparing IRRAflow versus standard EVD in treatment of IVH. Purchasing disposables.

3 Patients Enrolled





# Key Upcoming Corporate Milestones, 12-18 months

▶ Demonstrate commercial adoption with continued revenue growth

▶ Continue enrollment in clinical trials to document *IRRAflow* superiority



▶ Receive Hummingbird CE Mark and generate EU revenue



▶ Transition *IRRAflow* to MDR, Launch upgraded control unit with bedside monitor communication in Europe

*IRRAflow* Drainage  
Collection System



*IRRAflow*  
Software 4.0



# IRRAS well positioned for continued growth



## Increasing thought leader support, helping to grow pool of available clinical evidence

- Leading institutions on both sides of the Atlantic among early adopters with positive feedback and acceptance
- Initial case reports confirm product safety and efficacy in treating a broad range of intracranial pathologies with clear superiority to existing treatment options.

## Commercial launch ongoing with dedicated sales team in key markets and through selected distributors in Latin America, Middle East and parts of EU

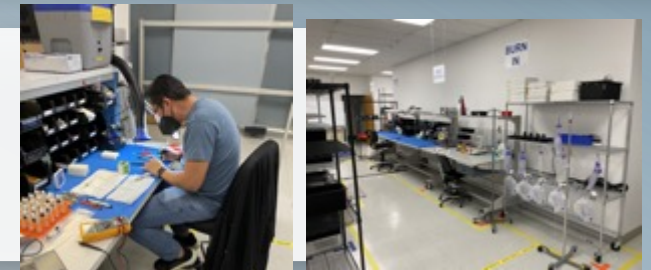
- Increasing trend of disposable reorders from existing customers confirm product adoption



## Attractive business model, confirmed by repeat orders of high margin consumables and driven by a growing installed base

## Ability to scale the business with In-house capital equipment manufacturing and strong contract manufacturing partners for disposables

- Noticeable progress shown on controlling costs, resulting in gross margin improvements



# IRRAS investment thesis stronger than ever

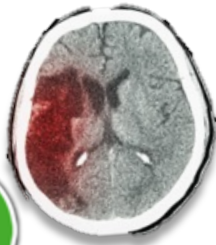
Despite challenges, IRRAS has removed barriers to growth and is primed for continued revenue growth moving forward



Innovative products address significant medical need in sizable addressable markets

Dedicated team of <50 employees in US & EU taking IRRAS to the next level

- Direct sales and education resources active in key markets



Limited product development and regulatory risk remains

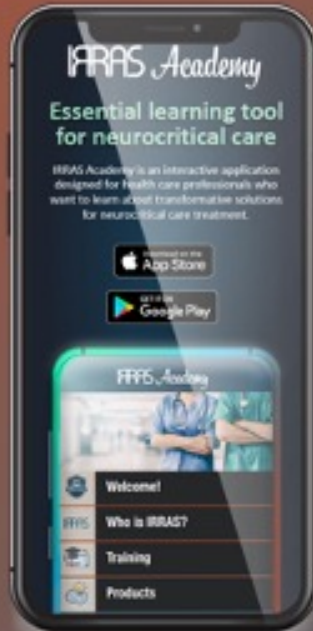
- Product utility validated with an increasing number of customers & patient treatments
- IRRASflow approved in key markets (US & EU) with additional markets to come (MDSAP)
- Hummingbird approved in the US, with an active CE Mark application underway
- Broad IP protection until 2038

# IRRAS

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