



# Commercial Operations Update

*December 2023*

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# Commercial Update – US Launch of ViraDx™ and FebriDx®



## AGENDA

- Overview of Products
- US Sales Channel Update
- Production Update
- ViraDx – US Commercial Update
- FebriDx – US Commercial Update
- Questions



# FebriDx – Lumos’ POC test to aid antibiotic prescribing

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- **FebriDx is an aid for healthcare providers to improve patient care and antibiotic stewardship**
  - FebriDx is a rapid, lateral flow, POC test that assists with differentiating between bacterial and non-bacterial infections
  - Very effective at ruling out bacterial infections — 98.7% NPV (negative predictive value) for bacterial infections
  - FebriDx provides a visual result within 10 minutes from a single drop of blood
  - Patients who do not have a bacterial infection will not get any benefit from taking antibiotics
  - Taking antibiotics can result in adverse patient reactions and contribute to antimicrobial drug resistance
  - 40% antibiotics prescribed in for respiratory infections unnecessary (ie. patient had no bacterial infection)<sup>1</sup>
- **FebriDx regulatory and commercial update**
  - FebriDx previously cleared in Europe, UK, Australia, Canada and other markets.
  - FDA clearance to market FebriDx as an aid in differentiating bacterial from non-bacterial acute respiratory infections awarded in June 2023
  - Achieved production and sales channel goals to enable commercial launch by end of CY 2023



<sup>1</sup> Tse, J.; Near, A.M.; Cheng, M.; Karichu, J.; Lee, B.; Chang, S.N. Outpatient Antibiotic and Antiviral Utilization Patterns in Patients Tested for Respiratory Pathogens in the United States: A Real-World Database Study. *Antibiotics* 2022, 11, 1058. <https://doi.org/10.3390/antibiotics11081058>

# ViraDx™ – Lumos' POC test for key respiratory infections



- **ViraDx highly relevant POC test for post-pandemic environment:**
  - SARS-CoV-2 pandemic increased consumer and healthcare POC testing
  - ViraDx is a 3-in-1 test for COVID-19/flu A/flu B
  - One of two tests available in market that provides visual read-out
- **ViraDx regulatory and commercial update:**
  - US EUA awarded in September 2023
  - CLIA waived – able be used in 260,000 clinics in the US



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# Production



- **Commercialisation activities for FebriDx and ViraDx previously on hold:**
  - Timing and likelihood of US regulatory clearances uncertain
  - Need to conserve cash reserves
  - Commenced commercial scale up activities in July 2023
- **Established commercial production to meet initial anticipated demand**
  - Sourced and ordered inventory of raw material
  - Established assembly and quality testing for both ViraDx and FebriDx
  - Finished product on the shelf ready for shipping
  - Aim to build out to 2-3 months inventory once market demand and seasonality is better understood



# Lumos' US Sales Channel

- **Established low-cost, high-reach US sales channel:**
  - Internal Commercial Operations Team:
    - Senior VP Commercial Operations, 4 direct reports
  - Eight Independent Commission-only sales representatives appointed
  - Distributors:
    - Over ten regional distributors appointed (Eg. Atlantic Medical Solutions, CLIA Waived, Inc, Mercedes Scientific, etc)
    - In discussions with large national distributors (Eg. Henry Schein, Fisher etc)
- **Building a product portfolio for the kit bag:**
  - Own products: ViraDx and FebriDx
  - In-licensed: Binx IO: CLIA-waived molecular test for chlamydia & gonorrhoea.
  - Will In-license additional products relevant to urgent care and physician office groups



# ViraDx – US Commercial Update

- **Positive market dynamics:**

- POC testing for respiratory infections well-established in US
- CDC reporting harsh influenza season this year with outpatient respiratory illness continuing to track above baseline (season continues until March)

- **Sales of ViraDx in the US have commenced:**

- First test lot released 21 November
- Pre-orders received and initial stocking orders have been shipped
- Approximately US\$150,000 sales revenue to date
- Reimbursement — coding is established and has been confirmed
- Eight distributor agreements executed targeting primary care, urgent care, employee health and student health
- Expansion plan includes and additional 8 distributor agreements





# FebriDx – US Commercial Update

- **Global threat of Antimicrobial Resistance (AMR) gaining attention:**
  - World AMR Awareness Week just finished (18-24 Nov)
  - Recognised overprescribing of antibiotics one of the key drivers of AMR
- **On track for sales to commence by year end:**
  - Pre-orders for FebriDx already received
  - First test lot expected to be released late December
  - Nine distributor agreements executed
  - Expansion plan includes additional 2-3 agreements from majors
  - Currently limited to use in CLIA moderately complex settings:
    - Large urgent care clinics
    - Outpatient clinics



# FebriDx – US Commercial Launch Activities

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- **CLIA status:**

- Currently can be used in CLIA Moderately Complex Settings (10,000 labs)
- Multiple paths to securing CLIA Waiver (260,000 clinical settings)

- **Reimbursement:**

- Two biomarker CPT codes identified – need to be tested
- American Medical Association approved Proprietary Laboratory Analyses (PLA) code

- **Marketing and education:**

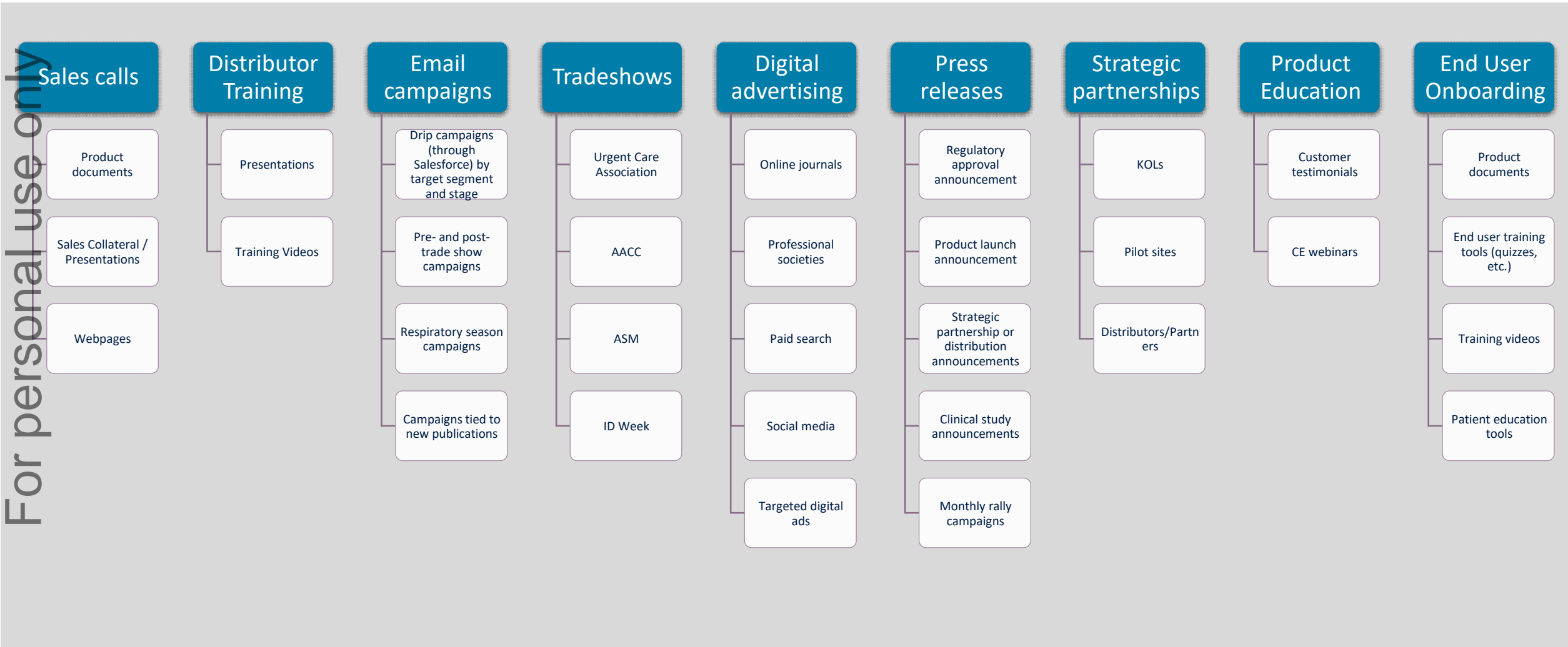
- Microbial testing prior to prescribing antibiotics not currently routine
- Assembling Medical Advisory Board of Urgent Care experts
- Program of communication through social media and KOLs



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# US FebriDx Marketing Activities — Overview

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# Questions