



### Fourth Quarter and Full Year 2023 Financial and Business Update

February 28, 2024

NASDAQ: AVIR

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#### **Industry Information**

Market data and industry information used throughout this presentation are based on management's knowledge of the industry and the good faith estimates of management. We also relied, to the extent available, upon management's review of independent industry surveys and publications and other publicly available information prepared by a number of third-party sources. All of the market data and industry information used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we believe that these sources are reliable, we cannot guarantee the accuracy or completeness of this information, and we have not independently verified this information. While we believe the estimated market position, market opportunity and market size information included in this presentation are generally reliable, such information, which is derived in part from management's estimates and beliefs, is inherently uncertain and imprecise. No representations or warranties are made by the Company or any of its affiliates as to the accuracy of any such statements or projections. Projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described above. These and other factors could cause results to differ materially from those expressed in our estimates and beliefs and in the estimates prepared by independent parties.

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### Strong Operational Execution in 2023 Leads to Anticipated Key Clinical Milestones in 2024

### COVID-19: 2023 Achievements Global Phase 3 SUNRISE-3 Program

- ✓ Achieved substantial enrollment progress
- $\checkmark\,$  Granted Fast Track Designation from FDA
- Expanded global footprint to target of ~300 clinical sites
- Broadened eligibility criteria of high-risk patients and increased sample size to address lower hospitalization and death rates
- ✓ In vitro studies confirmed bemnifosbuvir remains fully active against newest Omicron subvariants
- Presented and published preclinical and clinical data supporting program

### HCV: 2023 Achievements Global Phase 2 Program

- Regulatory approvals of short 8-week treatment of global Phase 2 combination trial of bemnifosbuvir + ruzasvir
- ✓ Completed enrollment of lead-in cohort of 60 patients
- Demonstrated potent *in vitro* synergy and compelling profile against major HCV resistant mutations
- Advanced fixed dose combination tablet program for Phase 3 program
- Presented and published preclinical and clinical data supporting program



## Focused Antiviral Pipeline, Fully Funded Through Key Inflection Points

### Key Clinical Data Expected in 2024: Phase 3 SUNRISE-3 Results and Final Phase 2 HCV Results

|   |  | <ul> <li>New : &gt;1,400 patients enrolled</li> <li>1<sup>st</sup> interim analysis (DSMB) March'24</li> <li>2<sup>nd</sup> interim analysis (DSMB) Q2'24</li> <li>Topline results 2H'24</li> <li>NDA submission target YE'24</li> </ul> |
|---|--|--|
|   |  | <ul><li>Protease inhibitor</li><li>Program update Mid'24</li></ul>   |
| 3 |  | <ul> <li>New data: lead-in cohort</li> <li>Lead-in cohort SVR4 final results</li> <li>Final Phase 2 SVR12 results 2H'24</li> <li>Phase 3 initiation target 2H'24</li> </ul>  |
|   |  |  |

Cash, cash equivalents & marketable securities: **\$578.1M at 12/31/23** -- Cash runway anticipated through 2026

\*Bemnifosbuvir (generic name for AT-527) is a double prodrug nucleotide analog. \*\* Worldwide exclusive license for all uses from Merck.

1. Bemnifosbuvir and ruzasvir have each separately generated clinical results and are being developed as a combination for HCV.



### HEPATITIS C

## Program Update: Potential Best-in-Class Pan-Genotypic Regimen

- Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir
- Final SVR4 Results From Lead-in Cohort



## HCV

# Continues to be a health crisis in US

Recognized ongoing unmet needs by US healthcare providers

UNMET MEDICAL NEED in US: ~ 2.4M estimated to have HCV

New and reinfection rates exceed cures

### **Best-in-Class Target Profile - Bemnifosbuvir + Ruzasvir**

- Potential short 8-week treatment with lower daily pill burden
- Potential for fewer side effects, low risk for drug-drug interactions and no food effect
- Protease inhibitor-free treatment

### **Global Market Opportunity:**

>**\$3B** net sales in 2023

Primarily 2 product market No competitors in clinical development



### **Market Research Shows Substantial Unmet Needs in HCV Treatments**

Only 6% of US Healthcare Providers Satisfied with Current Treatments





Information Based on Atea's Proprietary Quantitative Market Research Conducted in Nov '23

### Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir in HCV Patients

Study Design: Open label combinationN= up to 280: including a lead-in cohort



### **Patient Population:**

- HCV-infected patients, including compensated cirrhosis
- Direct-acting antiviral naïve
- All genotypes

### 60 Patient Lead-in Cohort:

- Safety and tolerability
- Sustained virologic response (SVR) at Week 4 post-treatment (SVR4)

### **Primary Endpoints:**

- SVR at Week 12 post-treatment (SVR12)
- Safety

### **Other Endpoints:**

- Virologic failure
- SVR at Week 24 post-treatment (SVR24)
- Resistance



## **Patient Demographics and Baseline Characteristics**

Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir Lead-in Cohort

| Patient Prof                       | ile   | Total (N=60)          |  |  |  |  |
|------------------------------------|---|-----------------------|--|--|--|--|
| Median age, yrs (range)            |   | 47 (25-79)            |  |  |  |  |
| Median BMI, kg/m <sup>2</sup> (ran | ge)   | 26.3 (18.9-47.1)      |  |  |  |  |
| Male/Female, n (%) / n (           | %)  | 34 (56.7) / 26 (43.3) |  |  |  |  |
|                                    | White   | 57 (95)               |  |  |  |  |
| Race, n (%)                        | Black   | 1 (1.7)               |  |  |  |  |
|                                    | Other   | 2 (3.3)               |  |  |  |  |
| DAA-naïve, n (%)                   |   | 60 (100)              |  |  |  |  |
|                                    | 1a  | 6 (10)                |  |  |  |  |
|                                    | 1b  | 38 (63.3)             |  |  |  |  |
| HCV genotype, n (%)                | 1*  | 1 (1.7)               |  |  |  |  |
|                                    | 2   | 2 (3.3)               |  |  |  |  |
|                                    | initial         initial <t< td=""><td>13 (21.7)</td></t<> | 13 (21.7)             |  |  |  |  |
|                                    | FO  | 9 (15)                |  |  |  |  |
|                                    | F1  | 26 (43.3)             |  |  |  |  |
| Fibrosis Stage, n (%)              | F2  | 15 (25)               |  |  |  |  |
|                                    | F3  | 10 (16.7)             |  |  |  |  |

- Lead-in cohort comprised of non-cirrhotic patients only
- Compensated cirrhotic patients will be enrolled in second part of Phase 2 study



\*unspecified subtype

### New Data: Final Results 98% SVR4 Post-Treatment

Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir Lead-in Cohort





LLOQ=Lower limit of quantification \*As available data does not include 1 subject who did not attend the SVR4 visit

## **On-Treatment Viral Kinetics – Individual Patient Data**

Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir Lead-in Cohort



- All patients (n=60) near or below LLOQ by Week 4
- Bemnifosbuvir + ruzasvir kinetics compare favorably to Mavyret<sup>1</sup>, the only approved 8-week treatment for HCV
- Very rapid kinetics across genotypes support an 8-week regimen



**LLOQ**=Lower limit of quantification

1. Sarrazin et.al; Presented at ID Week 2018

### **Safety Summary**

Phase 2 Open Label Study of Bemnifosbuvir + Ruzasvir Lead-in Cohort

- All patients (n=60) completed the 8-week treatment period
- Bemnifosbuvir + ruzasvir was generally safe and well tolerated
- No drug-related serious adverse events or premature treatment discontinuations
- No trends observed in adverse events (mostly mild) and safety laboratory parameters



## **Global Phase 2 Open Label Trial Update**

*Bemnifosbuvir + Ruzasvir: Potential Best-in-Class Pan-genotypic Regimen* 

Re-initiated patient enrollment in January 2024 to complete Phase 2 study (n= up to 280) Activating ~50 clinical sites in ~15 countries for completion of Phase 2 study

- **Preparing for Phase 3 study**, initiation anticipated 2H'24
- Fixed dose combination tablet clinical selection study ongoing in US

✓ Bemnifosbuvir is being developed as the most potent nucleotide inhibitor for HCV<sup>1</sup>

✓ **Ruzasvir**, an NS5A inhibitor, is a highly potent drug candidate<sup>2</sup>



### COVID-19

## Bemnifosbuvir Phase 3 Program



- COVID-19 Unmet Medical Need
- 2<sup>nd</sup> Major Milestone Achieved for Global Phase 3 SUNRISE-3 Trial



## COVID-19

**Continuing Threat, Particularly for Those Vulnerable to Severe Disease** 

*New, Safe and Well-Tolerated Oral Therapies Needed* 

### **UNMET MEDICAL NEED:**

- Drug-drug interactions
- Safety concerns
- Tolerability issues

### **Bemnifosbuvir Target Profile:**

- Low risk of drug-drug interactions
- Generally safe and well-tolerated
- Distinct mechanism of action with high barrier to resistance

### **Oral Antiviral Global Market Opportunity:**

product

market

~\$4-5B<sup>+</sup>

Opportunity to expand market with improved product profile



## **COVID-19: Unmet Medical Need Remains in High-Risk Population**

SUNRISE-3 **Only** Phase 3 Program in High-Risk Patients with Hospitalization as Primary Endpoint

- SUNRISE 3: Second Milestone Achieved: >1,400 patients enrolled in monotherapy arm
  - 1<sup>st</sup> interim analysis (DSMB) planned **March'24**
  - 2<sup>nd</sup> interim analysis (DSMB) planned **Q2'24**
- **~75%** of patients from US clinical sites
- Ongoing unmet medical need due to safety concerns, tolerability and drug-drug interactions associated with current oral antiviral options
  - CDC: high infection rates for winter respiratory season 2023/2024<sup>1</sup>
  - COVID-19 remains a major cause of respiratory virus-associated hospitalizations<sup>1</sup>
  - Low booster uptake: currently ~20% of US adults
  - Unmet medical need particularly important in most vulnerable patients including the elderly, immunocompromised and those with underlying risk factors





## **SUNRISE-3: Global Phase 3 Trial in High-Risk COVID-19 Outpatients** *Bemnifosbuvir – U.S. Fast Track Designation for COVID-19*

Randomization

Inclusion Criteria: High-risk outpatients with mild or moderate COVID-19, regardless of vaccination status; symptom onset ≤5 days before randomization

**Geography:** US, Europe, Japan and ROW

### Phase 3 Study Design:

- Randomized, double-blind, placebo-controlled
- Bemnifosbuvir or placebo initiated same time as locally available standard of care (SOC)
- Two study populations:
  - *supportive care monotherapy* (primary analysis)
  - *combination therapy* (secondary analysis, local SOC includes treatment with other antiviral drugs against COVID-19)
- Two interim analyses for DSMB review (safety, futility)

**High-risk outpatients:**  $\geq$ 70,  $\geq$ 55 w/ one+ risk factors,  $\geq$ 50 with two+ risk factors,  $\geq$ 18 immunocompromised conditions

### **Primary Endpoint:**

All-cause hospitalization or death through Day 29 in monotherapy population (n=approximately 2,200 patients)

### **Secondary Endpoints:**

• COVID-19 related hospitalizations and deaths

Bemnifosbuvir 550 mg BID + SOC

Placebo BID + SOC

5 days of dosing with BEM or placebo

- Medically attended visits
- Symptom rebound / relapse
- Viral load rebound



Enrollment

Ongoing





## US Oral Antiviral Market Opportunity for COVID-19



#### COVID-19

### **Robust US TRx Scripts of COVID-19 Oral Antivirals Reflects Demand**



#### US Demand: Monthly COVID-19 Oral Antiviral Prescriptions Dispensed (thousands)

Paxlovid Lagevrio



## US Market Expected to Remain a Long-Term Multi-Billion Dollar Opportunity



### **Expanded Market Opportunities**

Paxlovid<sup>™</sup> Drug-Drug Interactions are a Concern

## 590M

### Annual US retail prescriptions (2023)<sup>3</sup> for commonly used drug classes where Paxlovid DDI is a concern

seizure medications, anti-arrhythmics, statins, oral corticosteroids, cancer therapies, etc.

Better safety and tolerability profile could lead to broader use

Increased promotion & awareness



No testing needed for prescription



<sup>(1)</sup> IQVIA TRxs for Paxlovid and Lagevrio from Jan'23–Sep'23 annualized for full year

<sup>(2)</sup> Cost of Treatment per Rx

## **Financial Summary**



### **Financial Update Fourth Quarter and Full Year 2023**

#### **Condensed Consolidated Statement of Operations and Comprehensive Loss**

(in thousands, except share and per share amounts) (unaudited)

|  | Three Mor<br>Decem | nths Ended<br>Iber 31, | Year E<br>Decem | Year Ended<br>December 31, |  |  |
|--|--------------------|------------------------|-----------------|----------------------------|--|--|
|  | 2023               | 2022                   | 2023            | 2022                       |  |  |
| Operating expenses                     |                    |                        |                 |                            |  |  |
| Research and development               | \$ 35,045          | \$ 27,540              | \$ 114,243      | \$ 81,936                  |  |  |
| General and administrative             | 11,528             | 12,359                 | 49,919          | 48,714                     |  |  |
| Total operating expenses               | 46,573             | 39,899                 | 164,162         | 130,650                    |  |  |
| Loss from operations                   | (46,573)           | (39,899)               | (164,162)       | (130,650)                  |  |  |
| Interest income and other, net         | 7,758              | 5,591                  | 29,224          | 11,151                     |  |  |
| Loss before income taxes               | (38,815)           | (34,308)               | (134,938)       | (119,499)                  |  |  |
| Income tax benefit (expense)           | (349)              | (123)                  | (1,018)         | 3,590                      |  |  |
| Net loss                               | \$ (39,164)        | \$ (34,431)            | \$ (135,956)    | \$ (115,909)               |  |  |
| Other comprehensive income (loss):     |                    |                        |                 |                            |  |  |
| Unrealized gain (loss) on available-   |                    |                        |                 |                            |  |  |
| for- sale investments                  | 469                | 171                    | 891             | (684)                      |  |  |
| Comprehensive loss                     | \$ (38,695)        | \$ (34,260)            | \$ (135,065)    | \$ (116,593)               |  |  |
| Net loss per share – basic and diluted | \$ (0.47)          | \$ (0.41)              | \$ (1.63)       | \$ (1.39)                  |  |  |
| Neighted everyge number of common      |                    |                        |                 |                            |  |  |

Weighted-average number of common shares – basic and diluted



### **Financial Update Fourth Quarter and Full Year 2023**

Selected Condensed Consolidated Balance Sheet Data (in thousands)

(unaudited)

|                                       | Dece | mber 31, 2023 | December 31, 2022 |         |
|---------------------------------------|------|---------------|-------------------|---------|
| Cash, cash equivalents and marketable |      |               |                   |         |
| securities                            | \$   | 578,106       | \$                | 646,709 |
| Working capital(1)                    |      | 558,079       |                   | 642,444 |
| Total assets                          |      | 594,968       |                   | 666,708 |
| Total liabilities                     |      | 39,776        |                   | 26,136  |
| Total stockholders' equity            |      | 555,192       |                   | 640,572 |

(1) The Company defines working capital as current assets less current liabilities. See the Company's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2023 for further detail regarding its current assets and liabilities.





## **Closing Remarks**



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## Significant Near-term Clinical Milestones in 2024 Fully funded Through Key Inflection Points

|           | COVID-19 – Global Phase 3 SUNRISE-3 Trial                  |  |                                      |                                      |   |      |  |
|-----------|--|--|--------------------------------------|--------------------------------------|---|------|--|
| Sunrise-3 | 1 <sup>st</sup> interim<br>analysis<br>planned<br>March'24 | <sup>•</sup> 2 <sup>nd</sup> interim<br>analysis<br>planned<br>Q2'24 |                                      | NDA<br>submission<br>target<br>YE'24 |   |      |  |
|           | 2024   |  |                                      |                                      | 2   | .025 |  |
|           | Resumed<br>enrollment<br>Jan'24                            | Fixed<br>dose tablet<br>selection<br>Mid-2024                        | Final Ph 2<br>SVR12 results<br>2H'24 |                                      | <ul> <li>Ph 3</li> <li>Initiation</li> <li>target</li> <li>2H'24</li> </ul> |      |  |
|           | HCV – Global Phase 2 St                                    | udy  |                                      |                                      |   |      |  |



Cash, cash equivalents & marketable securities at 12/31/23 Cash runway anticipated through 2026





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