



Fourth Quarter and Full Year 2024 Earnings Supplemental Materials

March 5, 2025

Advancing medicines.
Solving problems.
Improving lives.





Disclaimer

Certain statements in this press release include “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the advancement and related timing of our product candidate Anaphylm™ (epinephrine) Sublingual Film through clinical development and approval by the FDA, including the timing of submission of pediatric clinical studies, and filing and acceptance of the NDA for Anaphylm with the FDA, and the following launch of Anaphylm, if approved by the FDA; a potential advisory committee for Anaphylm; timing of potential international regulatory filings for Anaphylm and market approval outside of the U.S. for our product candidate Libervant; the advancement, growth and related timing of our Adrenaverse™ pipeline of epinephrine prodrug product candidates, including AQST-108 (epinephrine) Topical Gel through clinical development and FDA regulatory approval process, including design and timing of clinical studies and possible timing of data, including those necessary to support the targeted indication of alopecia areata for AQST-108 and the potential market share that AQST-108 may achieve, if approved by the FDA and launched; the increased market demand for our product Libervant® (diazepam) Buccal Film for the label indicated epilepsy patients between the ages of two and five years; the potential benefits our products and product candidates could bring to patients; the achievement of clinical and commercial milestones; our future financial and operating results and financial position, including with respect to our 2025 financial outlook and estimated cash runway; and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with our development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans, including those relating to Anaphylm (including for pediatric patients), AQST-108, and our other product candidates; risks associated with our distribution work for Libervant, including any delays or changes to the timing, cost and success of our distribution activities and expansion of market access for Libervant to patients aged between two and five years; risk of delays in advancement of the regulatory approval process through the FDA of our product candidates, including the filing of the respective NDAs, for Anaphylm, AQST-108 or failure to receive FDA approval at all of any of these product candidates; risk of the Company’s ability to generate sufficient clinical data for approval of our product candidates, including with respect to our PK/PD comparability submission for FDA approval of Anaphylm; risks associated with our ability to address the FDA’s comments on our future clinical trials, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risks associated with the success of any competing products, including generics; risk that we may not succeed in appealing the ruling of the U.S. District Court of the District of Columbia that the FDA approval of Libervant for the label indicated epilepsy patients between the ages of two and five years was in error as a result of the current orphan drug market exclusivity granted by the FDA for a prior approved nasal spray product of another company for this patient population aged six years and older; risks and uncertainties inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risk of development of a sales and marketing capability for commercialization of our product Libervant and other product candidates, including Anaphylm and AQST-108; risks associated with the potential impact on the value of the Company of the sale or outlicensing of our product and product candidates, including Libervant and Anaphylm and other product candidates; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing, including under our ATM facility, and revenues from operations, to satisfy all of our short-term and longer-term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund commercialization activities relating to Libervant for patients between two and five years of age and to fund future clinical development and commercial activities for our product candidates; risk that our manufacturing capabilities will be insufficient to support demand for Libervant for patients between two and five years of age and for older patients, should Libervant receive U.S. market access for these older patients, and for demand for our licensed products in the U.S. and abroad; risk of eroding market share for Suboxone® as a sunset product, which accounts for a substantial part of our current operating revenue; risk of default of our debt instruments; risks related to the outsourcing of certain sales, marketing and other operational and staff functions to third parties; risks associated with the rate and degree of market acceptance in the U.S. and abroad of Libervant for label indicated epilepsy patients between two and five years of age, and for older label indicated epilepsy patients, if approved for U.S. market access and after the expiration of the orphan drug market exclusivity period in January 2027; risk of the rate and degree of market acceptance in the U.S. and abroad of Anaphylm, AQST-108 and our other product candidates, should these product candidates be approved by the FDA, and for our licensed products in the U.S. and abroad; risk associated with the size and growth of our product markets; risk associated with our compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to our products; risk that our patent applications for our product candidates, including for Anaphylm and AQST-108, will not be timely issued, or issued at all, by the U.S. Patent and Trademark Office; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business including relating to our products and product candidates and product pricing, reimbursement or access therefor; risk of loss of significant customers; risks related to claims and legal proceedings against us including patent infringement, securities, business torts, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; risks related to any disruptions in our information technology networks and systems, including the impact of cybersecurity attacks; risk of increased cybersecurity disruptions due to remote working arrangements; risk of adverse developments affecting the financial services industry; risks related to inflation and changing interest rates; risks related to the impact of other pandemic diseases on our business; risks and uncertainties related to general economic, political (including the Ukraine and Israel wars and other acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; risks related to uncertainty about presidential administration initiatives and their impact on our business; and other uncertainties affecting us including those described in the “Risk Factors” section and in other sections included in the Company’s 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the U.S. Securities and Exchange Commission. Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this presentation whether as a result of new information, future events or otherwise, except as may be required by applicable law.



Q4/FY 2024 earnings key messages



Anaphylm™ (epinephrine) Sublingual Film for severe allergic reactions, including anaphylaxis

- Positive topline results from OASIS study received in October 2024
- Successful Pre-NDA meeting in November 2024
- Initial pediatric clinical trial results in subjects 7-17 years of age in line with expectations
- NDA submission has begun and expected to be completed in the next several weeks
- Preparing for launch in Q1 2026, if approved by FDA

AQST-108 (epinephrine) Topical Gel for alopecia areata (AA)

- Successful Pre-IND meeting with the FDA completed in December 2024
- Plan to open the IND and initiate a Phase 2a study in Q2 2025

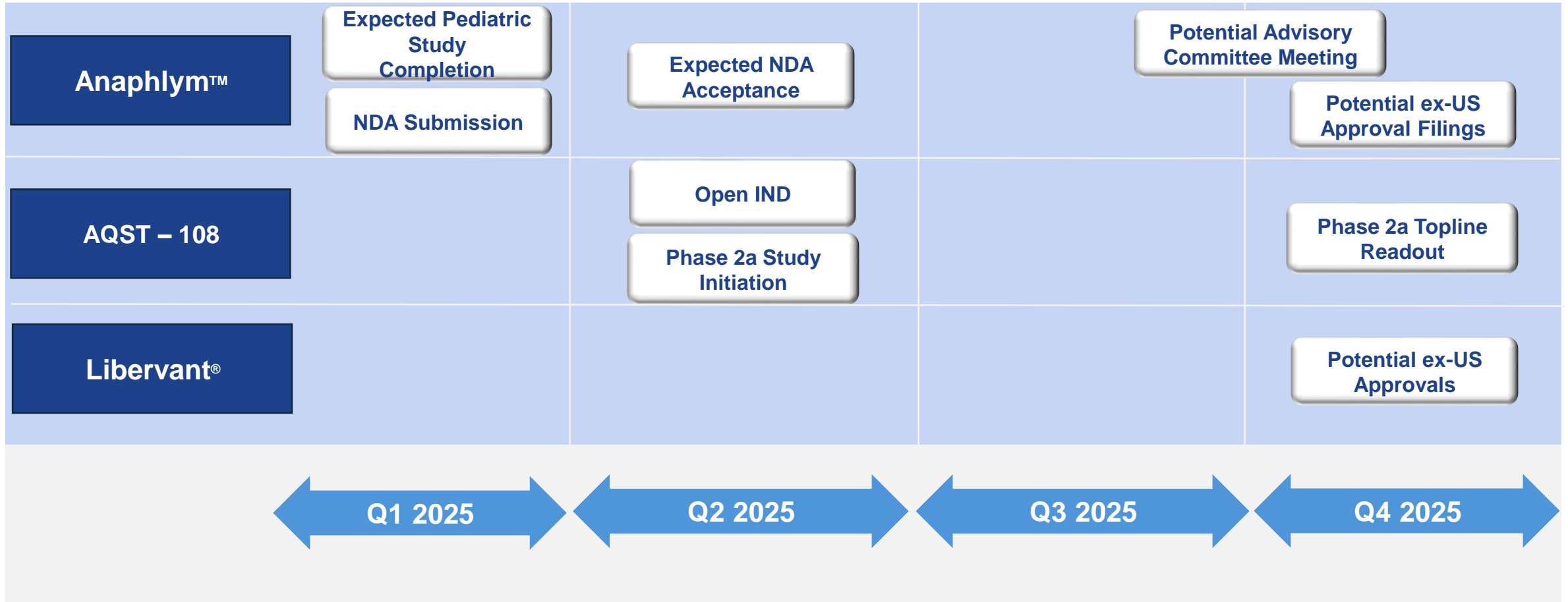
Libervant® (diazepam) Buccal Film for patients ages 2-5 years old (epilepsy)

- Payer coverage continues to improve; prescriptions continue to grow
- US District Court ruling against Libervant approval being appealed

Strong balance sheet with cash runway into 2026

- As of December 31, 2024, the Company had a proforma cash balance of approximately \$93 million¹

Upcoming expected key milestones

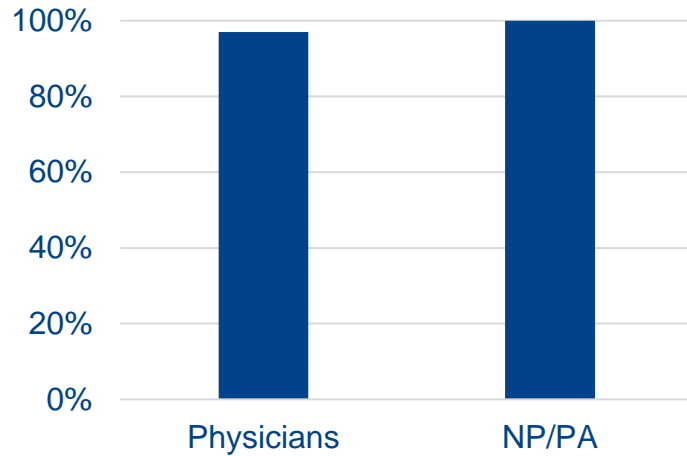




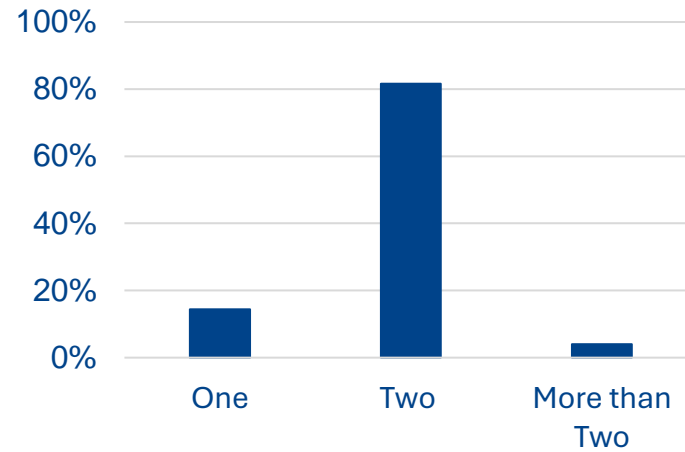
Anaphylm Awareness, Trial, and Usage (ATU) findings¹



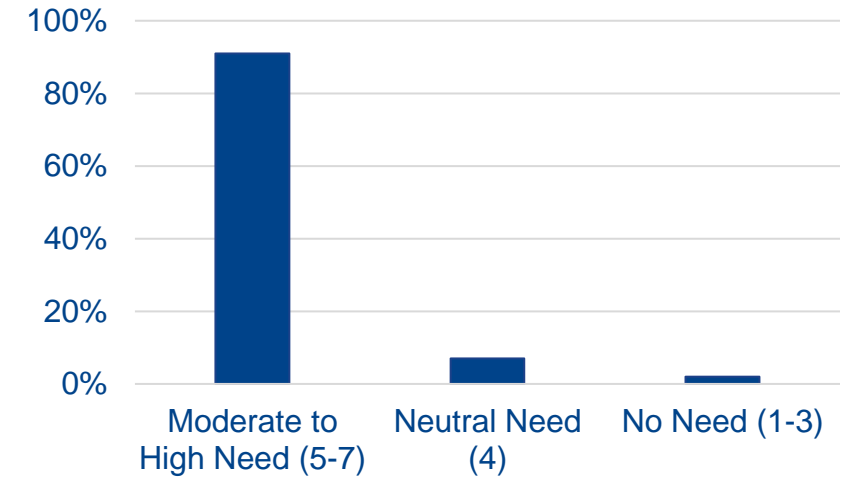
What % of time should patients carry their rescue medication?



How many rescue medications should be carried?



On a 1-7 scale, what is the need for a needle-less epinephrine product?



AQST-108 planned Phase 2a clinical study for alopecia areata¹

A Phase 2a, multi-center, double-blind, dose-response, adaptive study to evaluate the safety and efficacy of AQST-108 in patients with moderate alopecia areata

Phase 2a Study Design

- **36 subjects, 3 doses**
- **12 – 24 weeks²**
- **Early Responder Rate (ERR) of 10% (early responder defined as a subject with 20% improvement in SALT from baseline) at week 12**
- **Mean change from baseline in the Alopecia Density and Extent (ALODEX) score and PGI-C responses**

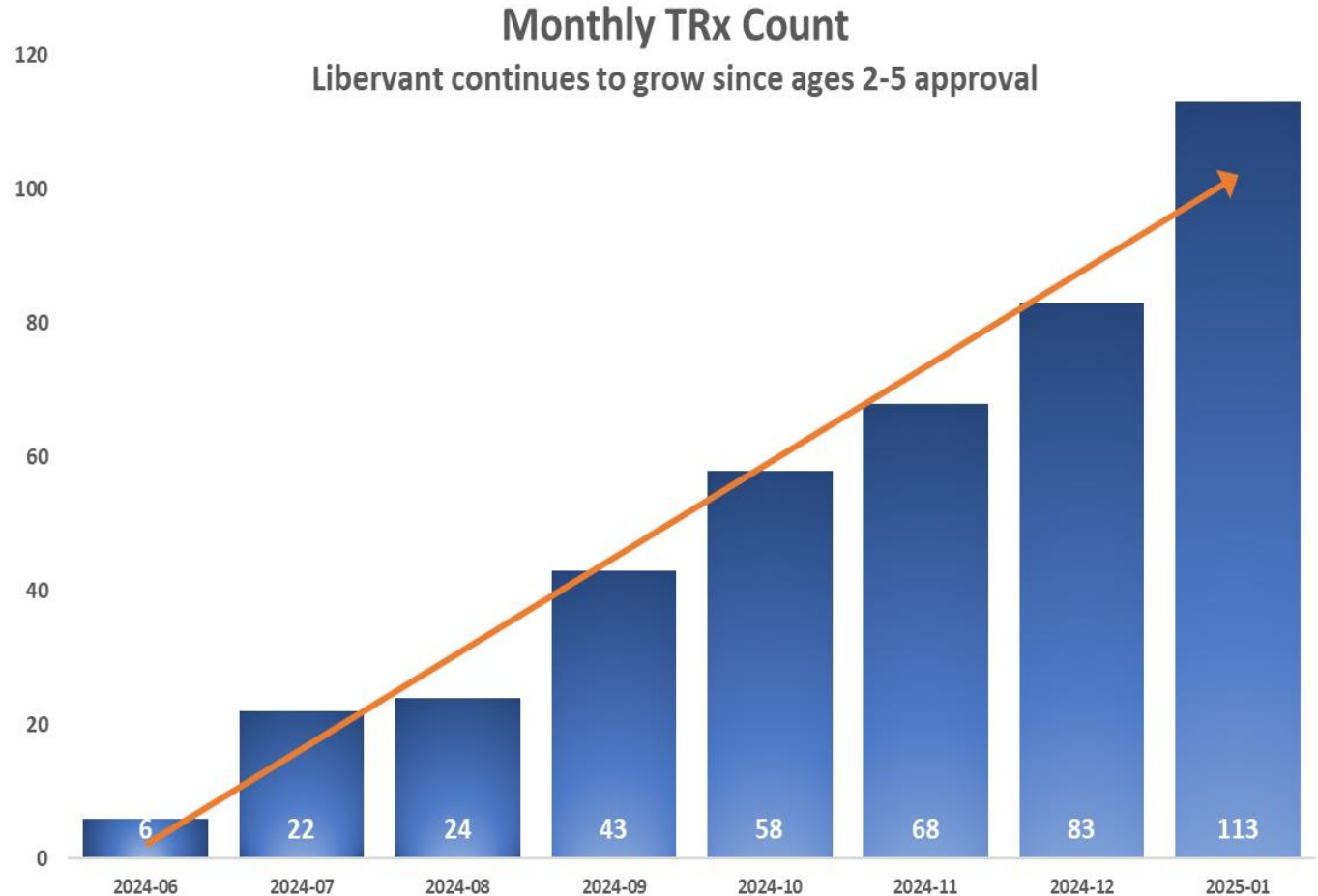
Phase 2a Study Objectives:

- Assess the safety and efficacy of AQST-108 in alopecia areata patients following 12 weeks of treatment as determined by change from baseline $\geq 10\%$ in SALT score at week 12



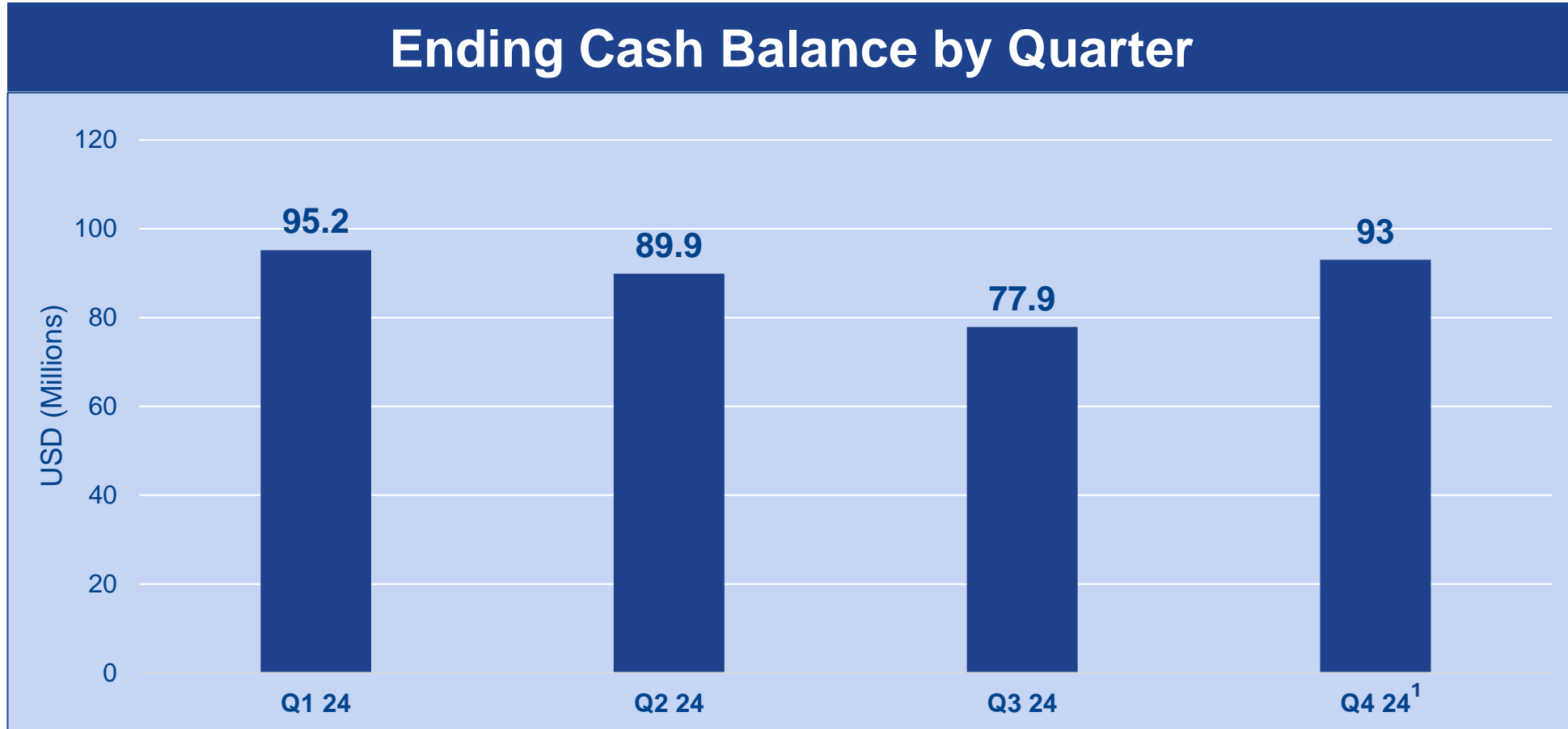
Libervant for patients aged two to five continues to grow¹

- Salesforce gaining traction with targeted HCPs
- Payor coverage continues to expand
 - Medicaid reimbursable in all states with clinically appropriate edits (e.g., age)
 - Negotiations completed with top three commercial pharmacy benefit managers
 - Commercial health plans continue to add coverage
 - Full nationwide retail distribution in place
- Now stocked at 70 regional wholesaler distribution centers across the U.S. for retail pharmacy access





Positioned to meet near term milestones with projected cash runway into 2026



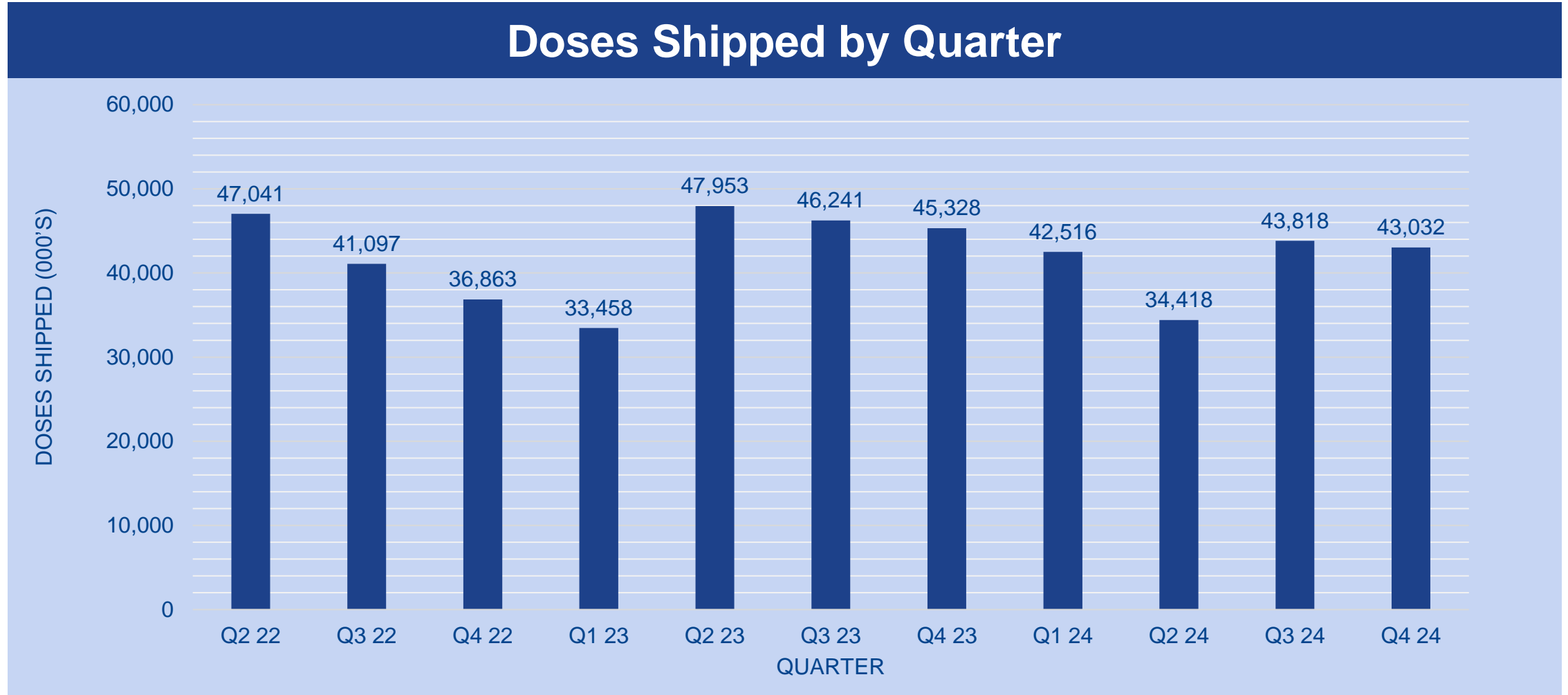
1. As of December 31, 2024, cash and cash equivalents was \$71.5 million. Proforma cash which includes capital net proceeds of \$21.4 million received on February 14, 2025 through the Company's "At-the-Market" (ATM) Facility.



Manufacturing operations continue to generate cash flow



Doses Shipped by Quarter



2024 Results

- Revenue of \$57.6 million
- Non-GAAP adjusted EBITDA loss was \$23 million

2025 Outlook

- Total revenues of approximately \$47-\$56 million
- Non-GAAP adjusted EBITDA loss of approximately \$46-\$53 million¹

Thank You