



Q4 2024 Earnings Supplemental Materials

March 5, 2024

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Disclaimer

Certain statements in this presentation 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 through clinical development and approval by the U.S. Food and Drug Administration (FDA), including receipt and release of topline data and the filing of the Anaphylm New Drug Application (NDA); regarding the 2024 financial outlook of the Company and its growth and future financial and operating results and financial position; and other statements that are not historical facts. These forward-looking statements are subject to the uncertain impact of the COVID-19 global pandemic on the Company’s business including with respect to its clinical trials including site initiation, enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approval of Anaphylm and Libervant and the Company’s other pipeline products, pharmaceutical ingredients and other raw materials supply chain, manufacture, and distribution; and ongoing availability of an appropriate labor force and skilled professionals. These forward-looking statements are based on the Company’s 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 the Company’s development work, including any delays or changes to the timing, cost and success of its product development activities and clinical trials for Anaphylm, Libervant and our other product candidates; risk of the Company’s ability to generate sufficient data in its PK/PD comparability submission for FDA approval of Anaphylm; risk of the Company’s ability to address the FDA’s comments on the Company’s pivotal PK study protocol and other concerns identified in the FDA End-of-Phase 2 meeting for Anaphylm, including the risk that the FDA may require additional clinical studies for approval of Anaphylm; risk of delays in or the failure to receive FDA approval of Anaphylm; risks associated with the Company’s development work, including any delays or changes to the timing, cost and success of the Company’s product development activities; risk of the success of any competing products; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks, and regulatory limitations); risk of the rate and degree of market acceptance of our product candidates, including Anaphylm and Libervant, and our licensed products in the U.S. and abroad; risk of insufficient capital and cash resources, including insufficient access to available debt and equity financing and revenues from operations, to satisfy all of the Company’s short-term and longer term liquidity and cash requirements and other cash needs, at the times and in the amounts needed, including to fund future clinical development activities for Anaphylm, Libervant and our other product candidates; risk of failure to satisfy all financial and other debt covenants and of any default under existing debt financing; risk that our manufacturing capabilities will be sufficient to support demand for existing and potential future licensed products in the U.S. and other countries; risk of eroding market share for Suboxone® and risk as a sunset product, which accounts for the substantial part of our current operating revenue; risk of the size and growth of our product markets; risks of 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 the Company’s products; risk of unexpected patent developments; uncertainties related to general economic, political (including acts of war and terrorism), business, industry, regulatory, financial and market conditions and other unusual items; and other risks and uncertainties affecting the Company 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.

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Q4 2023 Earnings: Key Messages

Financial Performance

- ❖ Exceeded our revenue and Non-GAAP Adjusted EBITDA guidance
- ❖ \$45MM debt refinancing resulted in cash savings of approximately \$28MM through June of 2025
- ❖ Finished the year with approximately \$24MM in cash

Anaphylm™ (epinephrine) sublingual film

- ❖ On track for submission of New Drug Application (“NDA”) before year end 2024
- ❖ Positive top-line data reported from pilot studies in 2023
- ❖ Pivotal trial commenced – first patient dosed in December of 2023 - top-line data expected in March of 2024

Libervant™ (diazepam) buccal film

- ❖ Submitted NDA for Libervant for patients between the ages of two and five years old
- ❖ PDUFA action date is April 28, 2024

Consistent Execution in Q4

December

- ❖ Anaphylm pivotal study commenced – top-line data expected in March of 2024
- ❖ Finished the year with approximately \$24MM in cash

November

- ❖ Completed \$45MM debt refinancing
- ❖ Presented positive data from Anaphylm pilot studies at America College of Allergy, Asthma, and Immunology Annual Meeting

October

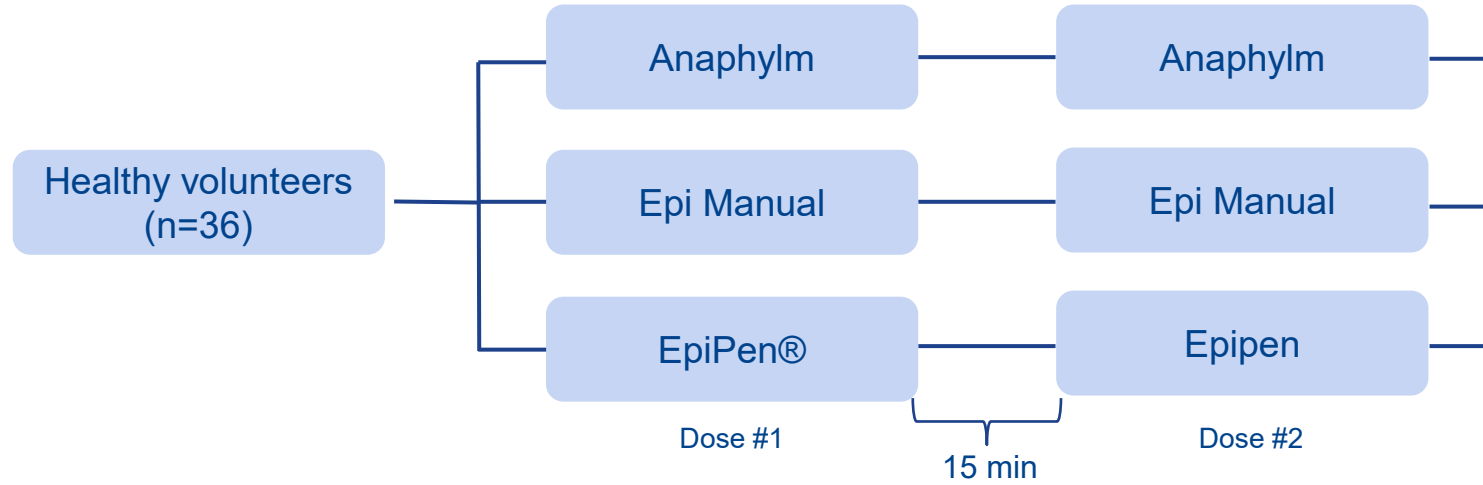
- ❖ Received positive FDA feedback on Anaphylm pivotal study protocol

Anaphylm Pivotal Study

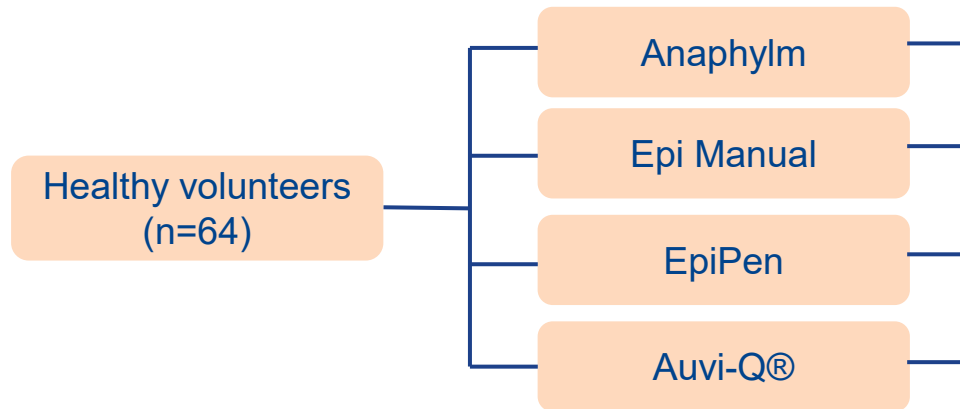
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Anaphylm Pivotal Study Design

Repeat Dose



Single Dose



Key Endpoints

Pharmacokinetic (PK)

- Maximum plasma concentration (C_{max})
- Time to maximum plasma concentration (T_{max})
- Partial area under the curve at 10, 20, 30, and 45 minutes

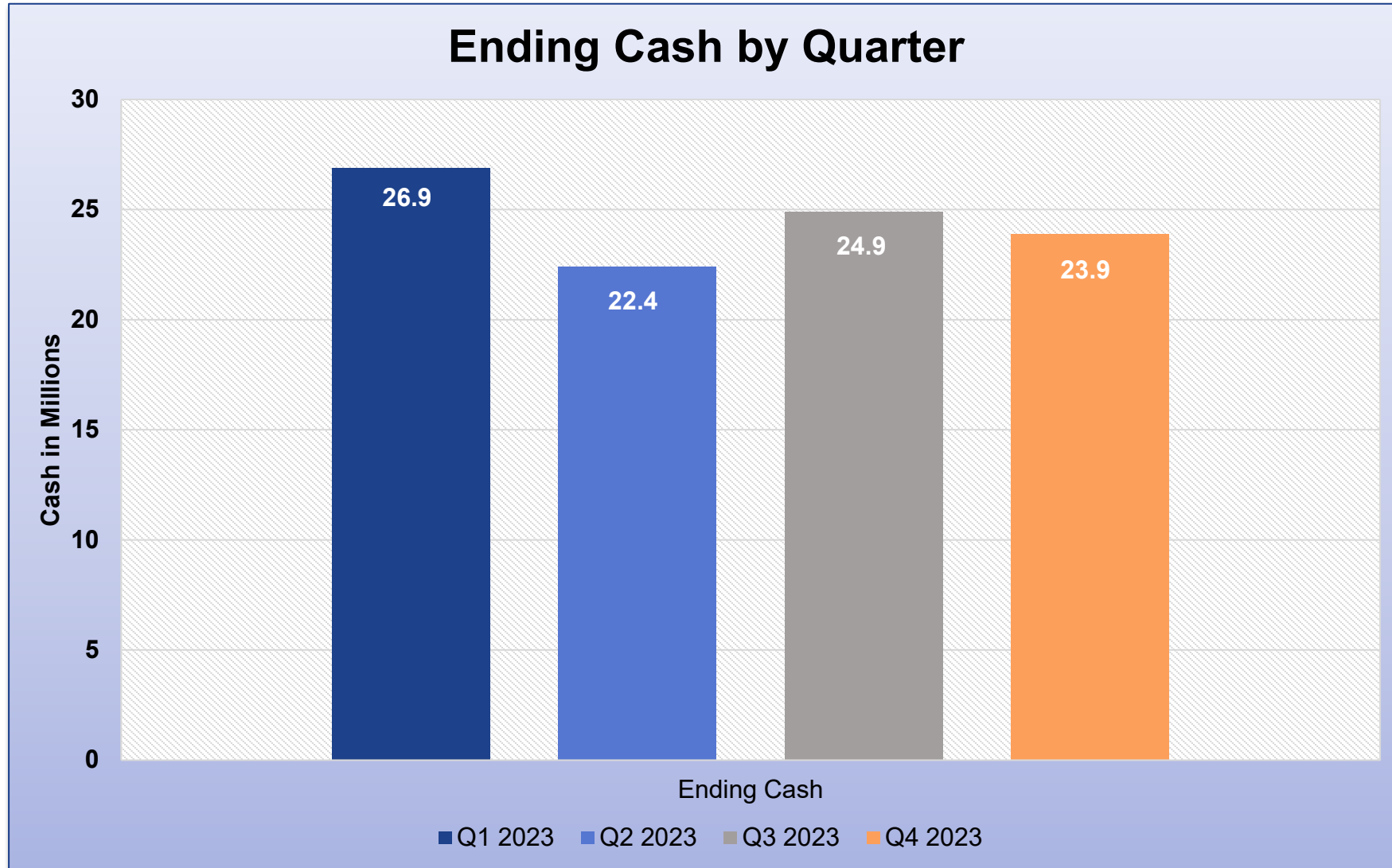
Pharmacodynamic (PD)

- Change in systolic blood pressure
- Change in diastolic blood pressure
- Change in heart rate

Financial Results

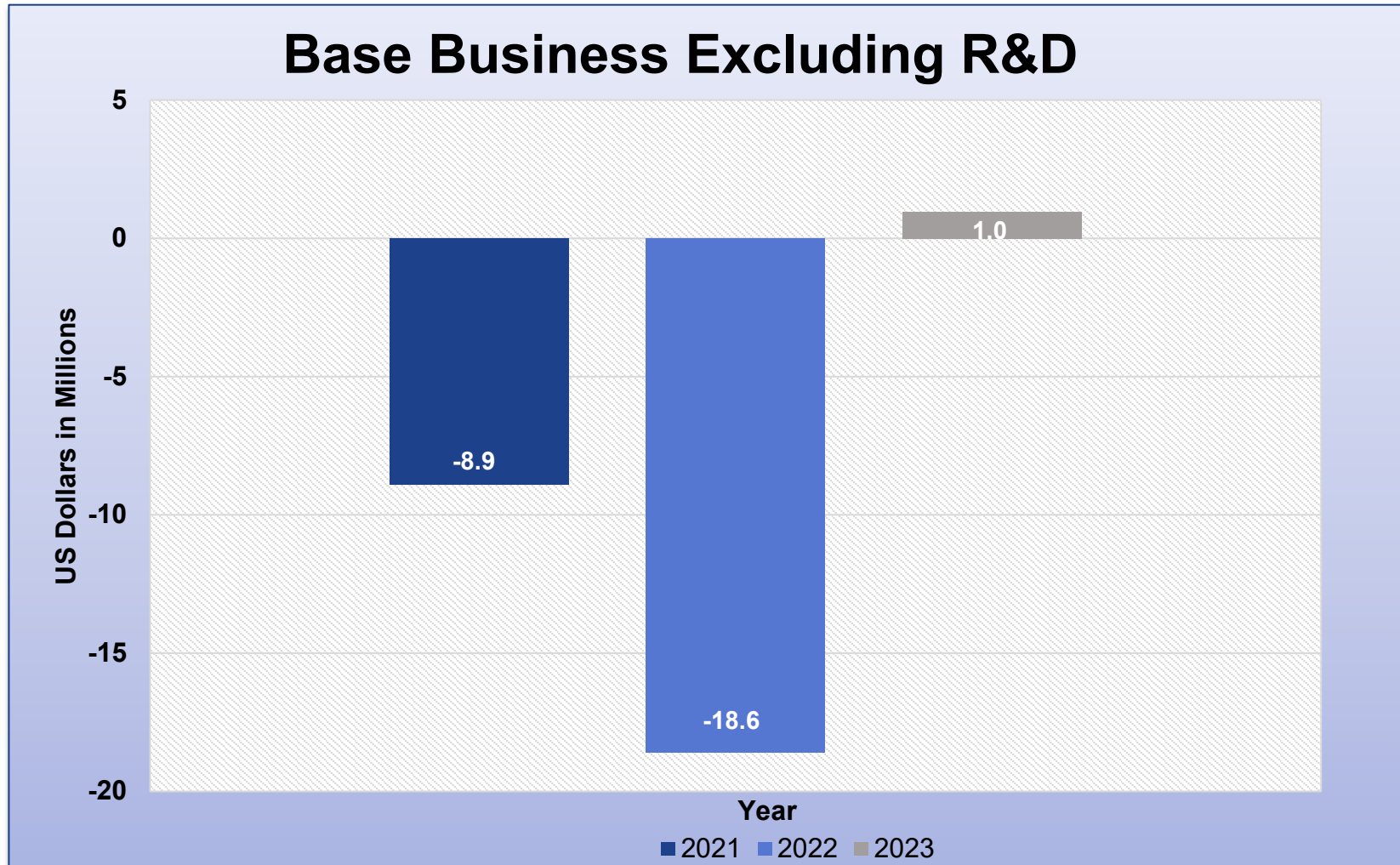
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Continuing to Manage Our Cash Position¹

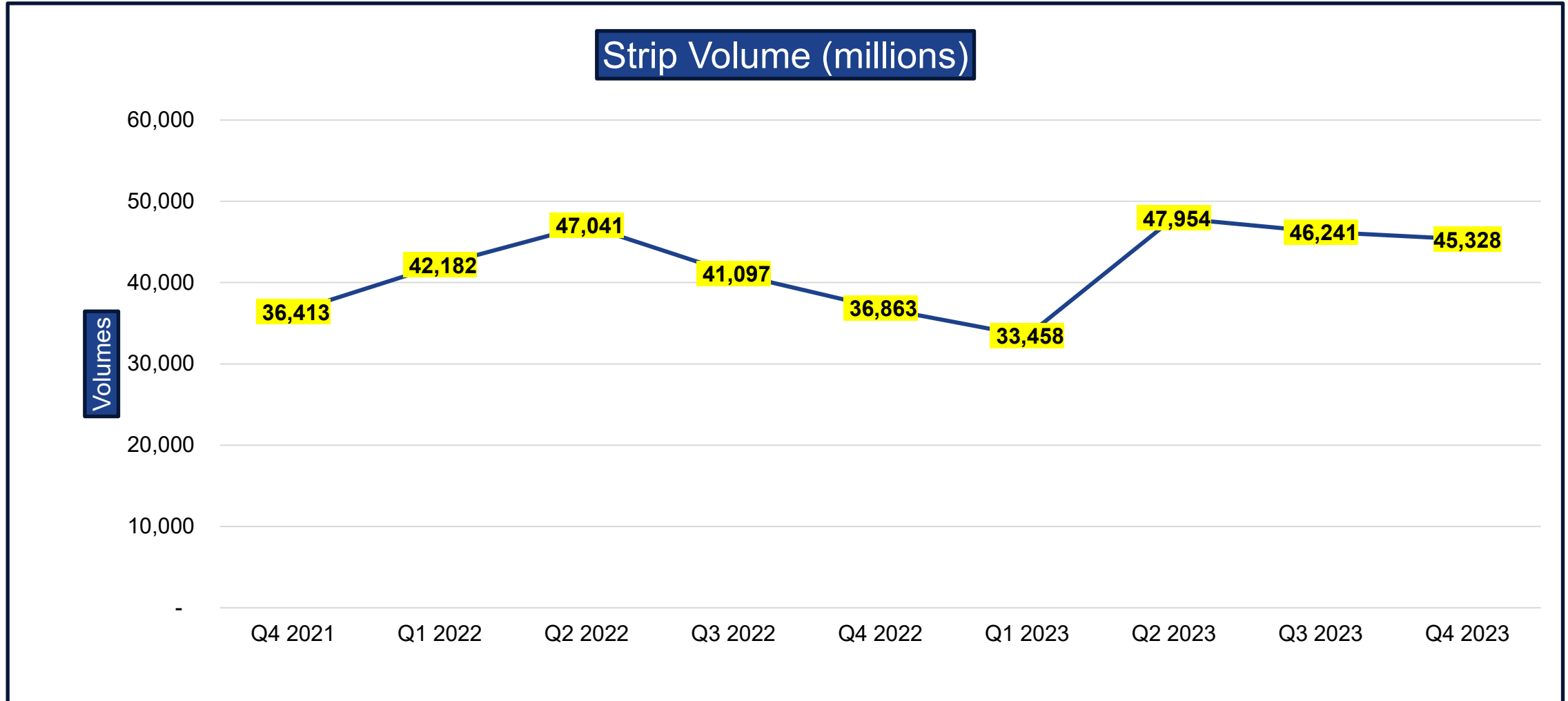


1. Principal and interest debt payments were made on October 2, 2023, when due.

Our Base Business Excluding R&D Expenses¹



Manufacturing Volumes Meet Expectations and Generate Cash Flow



2024 Outlook as of March 5, 2024

2024 Outlook

- Total revenues of approximately \$48 to \$51 million
- Non-GAAP adjusted EBITDA loss of approximately \$22 to \$26 million



Thank You

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