# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to

Commission File Number: 001-40021

# **AEON Biopharma, Inc.**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 85-3940478 (I.R.S. Employer Identification Number)

5 Park Plaza Suite 1750 Irvine, CA 92614 (Address of Principal Executive Offices)

(949) 354-6499 (Registrant's telephone number)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u> Class A common stock, \$0.0001 par value per share Trading symbol AEON

Name of Exchange on which registered
NYSE American

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  $\square$  No  $\boxtimes$ 

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  $\square$  No  $\boxtimes$ 

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes 🗵 No 🗆

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.  $\Box$ 

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.  $\Box$ 

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\ \square$  No  $\ \boxtimes$ 

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the registrant's Class A common stock on the last business day of the registrant's most recently completed second fiscal quarter was approximately \$17.0 million.

As of March 21, 2025, there were 10,532,802 of the registrant's shares of Class A common stock, \$0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2025 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission no later than 120 days after the registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Report") contains certain statements that are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Reform Act"). All statements other than statements of historical facts contained in this Report, including statements concerning possible or assumed future actions, business strategies, events or results of operations, and any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties and assumptions. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- the projected financial information, anticipated growth rate and market opportunities of AEON Biopharma, Inc. ("AEON");
- the ability to maintain the listing of Class A common stock on NYSE American;
- AEON's public securities' potential liquidity and trading;
- AEON's ability to raise financing in the future and to continue as a going concern;
- AEON's success in retaining or recruiting, or changes required in, officers, key employees or directors;
- factors relating to the business, operations and financial performance of AEON;
- the initiation, cost, timing, progress and results of research and development activities, preclinical studies or clinical trials with respect to AEON's current and potential future product candidates;
- AEON's ability to identify, develop and commercialize its main product candidate, botulinum toxin complex, ABP-450 (prabotulinumtoxinA) injection ("ABP-450");
- AEON's ability to obtain a Biologics License Application for therapeutic uses of ABP-450;
- AEON's ability to advance its current and potential future product candidates into, and successfully complete, preclinical studies and clinical trials;
- AEON's ability to obtain and maintain regulatory approval of its current and potential future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- AEON's ability to obtain funding for its operations;
- AEON's ability to obtain and maintain intellectual property protection for its technologies and any of its product candidates;
- AEON's ability to successfully commercialize its current and any potential future product candidates;
- the rate and degree of market acceptance of AEON's current and any potential future product candidates;
- regulatory developments in the United States and international jurisdictions;
- potential liability, lawsuits and penalties related to AEON's technologies, product candidates and current and future relationships with third parties;
- AEON's ability to attract and retain key scientific and management personnel;
- AEON's ability to effectively manage the growth of its operations;

- AEON's ability to contract with third-party suppliers and manufacturers and their ability to perform adequately under those arrangements, particularly its license and supply agreement with Daewoong Pharmaceutical Co., LTD. (the "Daewoong Agreement");
- AEON's ability to compete effectively with existing competitors and new market entrants;
- potential effects of extensive government regulation;
- AEON's future financial performance and capital requirements;
- AEON's ability to implement and maintain effective internal controls;
- the impact of supply chain disruptions; and
- the impact of macroeconomic developments beyond our control, such as health epidemics or pandemics, macro-economic uncertainties, social unrest, hostilities, natural disasters or other catastrophic events, on AEON's business.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. We have based these forward-looking statements on our current expectations, assumptions, estimates and projections. While we believe these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond our control. These and other important factors, including those discussed in this Report, may cause our actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. The forward-looking statements included elsewhere in this Report are not guarantees of future performance and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements included elsewhere in this Report. In addition, even if our results of operations, financial condition and liquidity, and events in the industry in which we operate, are consistent with the forward-looking statements included elsewhere in this Report, they may not be predictive of results or developments in future periods.

Any forward-looking statement that we make in this Report speaks only as of the date of such statement. Except as required by law, we do not undertake any obligation to update or revise, or to publicly announce any update or revision to, any of the forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Report. For all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Reform Act.

As used in this Report, unless otherwise stated or the context otherwise requires: "we," "us," "our," "AEON," the "Company," and similar references refer to AEON Biopharma, Inc. and its subsidiaries, and "common stock" refers to our Class A common stock.

#### RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in the "*Risk Factors*" section of this Annual Report. You should carefully consider these risks and uncertainties when investing in our common stock. Some of the principal risks and uncertainties include the following:

- Our management has concluded that uncertainties around our ability to raise additional capital raise substantial doubt about our ability to continue as a going concern. We will require additional financing to fund our future operations. Any failure to obtain additional capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our operations.
- Our future success currently depends entirely on the successful and timely regulatory approval and commercialization of our only product candidate, ABP-450. The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ABP-450 on a timely basis or at all.
- Clinical product development involves a lengthy, expensive and uncertain process. We may incur greater costs than we anticipate or encounter substantial delays or difficulties in our clinical studies.
- Even if ABP-450 receives regulatory approval for any of our proposed indications, it may fail to achieve the broad degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- ABP-450, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion.
- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop ABP-450 in any of our proposed therapeutic indications, conduct our clinical studies and commercialize ABP-450.
- We rely on the Daewoong Agreement to provide us exclusive rights to commercialize and distribute ABP-450 in certain territories. Any termination or loss of significant rights, including exclusivity, under the Daewoong Agreement would materially and adversely affect our development or commercialization of ABP-450.
- We currently rely solely on Daewoong to manufacture ABP-450, and as such, any production or other problems with Daewoong could adversely affect us. The manufacture of biologics is complex and Daewoong may encounter difficulties in production that may impact our ability to provide supply of ABP-450 for clinical studies, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, which, if approved, could be delayed or stopped.
- Third-party claims of intellectual property infringement, misappropriation or violation, or challenges related to the invalidity or unenforceability of any issued patents we may obtain or in-license may prevent or delay our development and commercialization efforts or otherwise adversely affect our results of operations.
- Our business and products are subject to extensive government regulation.
- Legislative or regulatory healthcare reforms in the United States and other countries may make it more difficult and costly for us to obtain regulatory clearance or approval of ABP-450 and to produce, market, and distribute our products after clearance or approval is obtained.
- The price of our common stock may be volatile.
- Sales of a substantial number of our securities in the public market by our existing securityholders could cause the price of our common stock and warrants to fall.
- We will require additional capital, which additional financing may result in restrictions on our operations or substantial dilution to our stockholders, to support the growth of our business, and this capital might not be available on acceptable terms, if at all.

#### PART I

#### Item 1. Business

AEON Biopharma, Inc. ("AEON") is a biopharmaceutical company focused on developing its proprietary botulinum toxin complex, ABP-450 (prabotulinumtoxinA) injection ("ABP-450"), for debilitating medical conditions.

On December 12, 2022, AEON Biopharma Sub, Inc. (formerly known as AEON Biopharma, Inc.) ("Old AEON") and Priveterra Merger Sub, Inc., a wholly owned subsidiary of Priveterra Acquisition Corp. ("Priveterra"), a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, or other similar business combination with one or more target businesses, entered into a Business Combination and Merger Agreement (the "Business Combination Agreement" or "BCA") dated December 12, 2022 and amended April 27, 2023.

On July 21, 2023 (the "Closing Date"), the parties consummated the transactions contemplated by the BCA (collectively referred to as the "Merger" or "Business Combination") in connection with the closing of the Merger (the "Closing"). On the Closing Date, Old AEON merged with Priveterra Merger Sub, Inc., with Old AEON surviving the merger as a wholly-owned subsidiary of the Company; and the Company changed its name from "Priveterra Acquisition Corp." to "AEON Biopharma, Inc."; and Old AEON changed its name to AEON Biopharma Sub, Inc. The post-Merger Company is referred to herein as "AEON," or the "Company."

Following the Closing, the Company's common stock is listed on the NYSE American under the symbol "AEON" and commenced trading on July 24, 2023.

Unless the context otherwise requires, references to "we", "us", "our" and "the Company" refer to the business and operations of AEON Biopharma, Inc. and its consolidated subsidiaries prior to the Merger ("Old AEON" or the "Predecessor") and to AEON Biopharma, Inc. ("AEON") following the consummation of the Merger.

#### Overview

We are a clinical stage biopharmaceutical company focused on developing our botulinum toxin complex, prabotulinumtoxinA injection ("ABP-450"), for debilitating medical conditions, with an initial focus on the neurosciences market. We plan to develop and seek regulatory approval of ABP-450 as a biosimilar product in the United States through submission of a Biologics License Application, or BLA, under Section 351(k) of the Public Health Service Act, or a Section 351(k) BLA, with the goal of addressing the estimated \$3.0 billion global therapeutic botulinum toxin market, which is projected to grow to \$4.4 billion in 2027, according to the Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global as of 2021. ABP-450 is the same botulinum toxin complex that is currently approved as a biosimilar in Mexico and India and, in the U.S. is approved to provide temporary improvement in the appearance of moderate to severe glabellar lines for certain adult patients and marketed by Evolus, Inc. under the name Jeuveau in the United States and Nuceiva in Canada and the European Union. We have exclusive development and distribution rights for certain therapeutic uses of ABP-450 in the United States, Canada, the European Union, the United Kingdom, and certain other international territories. We have built a highly experienced management team with specific experience in biopharmaceutical and botulinum toxin development and commercialization.

We have completed a Phase 2 study of ABP-450 for the treatment of cervical dystonia and completed enrollment and dosing of patients for a Phase 2 double blind study of ABP-450 for the treatment of both chronic and episodic migraine. We originally intended to pursue a submission of a BLA under Section 351(a) of the Public Health Service Act, or an Original BLA, seeking one or more potential therapeutic indications for ABP-450. However, our Phase 2 clinical trials for episodic and chronic migraine did not meet their respective primary endpoints. In May 2024, we announced the discontinuation of our Phase 2 clinical trials for episodic and chronic migraine in order to implement certain cash preservation measures. On July 9, 2024, we announced a strategic reprioritization to pursue a 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product for all of the indications for which Botox is approved, other than the cosmetic uses (for which we do not hold development or commercialization rights).

We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on the next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies.

Botulinum toxins have proven to be a highly versatile therapeutic biologic, with over 230 potential therapeutic uses documented in published scientific literature and twelve approved therapeutic indications in the United States. Our initial development programs for ABP-450 were directed at migraine, cervical dystonia and gastroparesis. We selected these initial programs based on a comprehensive product assessment screen designed to identify indications where we believe ABP-450 has the potential to deliver significant value to patients, physicians and payors and where its clinical, regulatory and commercial characteristics suggest viability. We believe that ABP-450 has potential across a broad range of target indications and we plan to continue to explore additional development programs that satisfy our product assessment screens.

The FDA allowed our Investigational New Drug application, or IND, for ABP-450, supporting our clinical trials in the preventative treatment for migraines, to proceed in October 2020, and we began treating patients in our Phase 2 clinical study beginning in March 2021. Prior to commencing this Phase 2 study, no Phase 1 clinical studies of ABP-450 had been performed in regard to migraine by us or any other party. Nevertheless, given the extensive preclinical toxicology and other data developed by our licensing partner, Daewoong, and the aesthetic licensor of ABP-450, Evolus, the FDA permitted us to proceed directly to this Phase 2 clinical trial.

The FDA allowed our IND for ABP-450, which supports our clinical trials in cervical dystonia, to proceed in October 2020, and we began treating patients in our Phase 2 clinical study beginning in April 2021. We enrolled 59 patients in this randomized, double-blind, placebo-controlled study across approximately 20 study sites in the United States. Patients enrolled into the study received one of four different injection cycles, low dose of 150 units, mid-dose of 250 units, high dose of 350 units or placebo, with patients evenly split among the four arms. Topline data from the Phase 2 cervical dystonia study, released in September 2022, showed that ABP-450 met all primary endpoints and a number of other key secondary endpoints, supporting the further development of ABP-450 in reducing signs and symptoms associated with cervical dystonia. We may commence a Phase 3 study in cervical dystonia pending the results of the comparative analytical studies and discussions with the FDA in a Biological Product Development meeting.

In December 2020, we initiated a preclinical gastroparesis study with 42 primates receiving multiple injections of ABP-450 across four dose ranges. The objective of this preclinical study was to characterize the safety and toxicology prior to entering human studies. We completed this preclinical study in January 2022. Following the preclinical study, we submitted an IND to the FDA and received a letter in May 2022 confirming that the IND-opening Phase 2a clinical study may proceed. We continue to evaluate various pathways to most efficiently advance this clinical development program.

Additionally, we have an ongoing preclinical study in rats designed to provide IND supporting safety and efficacy data. ABP-450 is injected into the stellate ganglion using ultrasound guidance to assess the effect on the sympathetic nervous pathway, which may inform us whether ABP-450 has the potential for utility across a broad portfolio of neuropsychiatric disorders, including post-traumatic stress disorder (PTSD). We may initiate other preclinical studies from time to time to evaluate the potential safety and efficacy of ABP-450 in other disorders.

We license ABP-450 from Daewoong, a South Korean pharmaceutical manufacturer, and have exclusive development and distribution rights for therapeutic indications in the United States, Canada, the European Union, the United Kingdom, and certain other international territories. Daewoong licenses the same 900 kDa botulinum toxin to Evolus for cosmetic indications, which Evolus markets and sells under the name Jeuveau in the United States and Nuceiva in Canada and the European Union. Prior to licensing the botulinum toxin complex to Evolus, Daewoong conducted a broad preclinical development program for ABP-450 that was primarily focused on safety to support any clinical indication. Subsequently, Evolus completed a comprehensive clinical development program of the same botulinum toxin complex and has received approval from regulatory authorities in the United States, the European Union and Canada to market and sell Jeuveau in the United States and Nuceiva in Canada and the European Union for the temporary improvement in the appearance of moderate to severe glabellar, or frown, lines in adults. Over 2,100 adult subjects with moderate to severe glabellar lines at maximum frown participated in Evolus' clinical development program, and each of Evolus' Phase 3 clinical studies successfully met their respective primary safety and efficacy endpoints. While none of these preclinical or clinical programs specifically contemplated any therapeutic use of ABP-450, given that the FDA's regulatory requirements are generally the same for the cosmetic or therapeutic use of a toxin, we believe that the positive data derived from these preclinical and clinical studies will support the clinical development and anticipated future safety labeling of ABP-450 for migraine and cervical dystonia, in addition to other indications, at all contemplated dose ranges.

We plan to pursue approval of a BLA under Section 351(k) that exclusively contemplates therapeutic indications for ABP-450, which we believe could improve reimbursement amounts for ABP-450, if approved. Existing botulinum toxins, including Botox, are approved under a single BLA for both therapeutic and cosmetic indications. As a result, other botulinum toxins are required to include the sales prices of both therapeutic and cosmetic botulinum toxin sales when calculating the average selling price, or ASP, that is used to determine the reimbursement amount physicians receive for therapeutic usage. The inclusion of a lower cosmetic sales price in the calculation of ASP can cause physicians to lose money when treating patients with existing botulinum toxins and also creates a deterrent to providing payors and/or providers with rebates or other financial incentives. If we are successful in obtaining a BLA under Section 351(k) for therapeutic indications of ABP-450, the ASP for ABP-450 would be calculated using only therapeutic sales, which we believe would facilitate consistent and favorable reimbursement to physicians when they choose to use ABP-450 for therapeutic treatments, as well as the ability to provide payors and/or providers with rebates and other financial incentives. This pricing model would be unique to us within the current therapeutic neurotoxin market, and we believe it would allow physicians to provide treatment with ABP-450 at a more competitive or the same net price as the market leader after rebates and discounts.

We believe ABP-450 could have therapeutic applications in a broad range of debilitating medical conditions, and we intend to continue to leverage our product assessment screening process to identify additional indications for future development. Our management team possesses significant and relevant experience in the botulinum toxin industry in both drug development and commercialization, and we believe they are highly qualified to successfully develop and commercialize ABP-450 to enhance the lives of patients that suffer from debilitating medical conditions.

# Overview of the Therapeutic Botulinum Toxin Market

Botulinum toxins are a standard treatment for a number of indications, including debilitating movement disorders, chronic migraine, overactive bladder, excessive salivating and excessive sweating, and are the first-line standard of care for the treatment of certain conditions, including cervical dystonia. The use of botulinum toxins to treat debilitating medical conditions began with the FDA approving Botox for the treatment of strabismus and blepharospasm, two eye muscle disorders, in adults, in 1989. Botox was the only FDA-approved type-A botulinum toxin until 2009 when the FDA initially approved Dysport for the treatment of cervical dystonia and glabellar lines in adults. In 2010, the FDA approved Xeomin for the treatment of cervical dystonia and blepharospasm in adults. There are currently nine unique therapeutic indications for botulinum toxins that have been approved by the FDA.

The global therapeutic botulinum toxin market is forecast to grow from \$3.0 billion in 2020 to an estimated \$4.4 billion in 2027, according to the Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global as of 2021. This market growth is expected to be driven primarily by growth in the number of procedures, which is expected to grow from 2.7 million in 2020 to an estimated 5.0 million in 2027, as well as multiple other factors. The global therapeutic toxin market is concentrated in the United States, which has an estimated 84% market share, while the European Union has an estimated 9% market share and Asia Pacific has an estimated 7% market share. The United States is projected to continue to be the largest market for therapeutic botulinum toxin treatment, primarily due to the greater number of approved indications, higher ASP, and greater patient and physician awareness of botulinum toxin usage. The global therapeutic toxin market also further breaks down by indication, with migraine comprising approximately 36% of the market share, spasticity comprising approximately 28% of the market share, cervical dystonia comprising approximately 17% of the market share, overactive bladder comprising approximately 6% of the market share and other indications comprising approximately 13% of the market share.

According to Decision Resources Group, Botox, Dysport and Xeomin collectively made up over 98% of the United States therapeutic market for botulinum toxins in 2021. The market leader for therapeutic botulinum toxins is Botox, which is marketed by AbbVie Inc., or AbbVie, and had approximately 85% of the global therapeutic market share for botulinum toxins and 95% of the United States therapeutic market share for botulinum toxins in 2019. The migraine indication is AbbVie's single largest toxin therapeutic indication and contributes to 45% of AbbVie's therapeutic toxin sales. The main approved competitors to Botox are Dysport, marketed by Ipsen Ltd., and Xeomin, marketed by Merz Pharmaceuticals, LLC, each of which have approximately 2% of the global market share for therapeutic botulinum toxin treatments.

#### Overview of ABP-450

ABP-450 is a 2-chain polypeptide, a heavy chain joined by a bond to a light chain. The light chain is a protease enzyme that attacks fusion proteins at the neuromuscular junction, preventing the vesicles containing acetylcholine from anchoring to the

membrane and inhibiting their release. ABP-450 interferes with nerve impulses by inhibiting the release of acetylcholine into the neuromuscular junction, causing a flaccid paralysis of muscles.

The active biologic ingredient in ABP-450 is Clostridium *botulinum* toxin, type A with a complete molecular complex weight of 900 kDa. Botulinum toxin type A is an active toxin composed of a covalently bonded dimer of two complexes consisting of neurotoxin, non-toxic non-haemagglutinin protein, and haemagglutinin proteins. The active part of the botulinum toxin is the 150 kDa component, and the remaining 750 kDa of the complex is made up of accessory proteins that we believe help with the function of the active portion of the botulinum toxin. When injected at therapeutic levels, ABP-450 blocks peripheral acetylcholine release at presynaptic cholinergic nerve terminals by cleaving SNAP-25, a protein integral to the successful docking and release of acetylcholine from vesicles situated within the nerve endings leading to denervation and relaxation of the muscle. ABP-450, if approved, will be the only therapeutic botulinum toxin with significantly similar physiochemical properties as Botox. In addition, ABP-450 will be the only therapeutic botulinum toxin that shares the same procedure and dilution ratios for the reconstitution of the botulinum toxin to an injectable liquid. These reconstitution procedures are not subject to intellectual property protection. We believe the similarity of the two products will facilitate physician adoption of ABP-450 more rapidly and sustainably than other botulinum toxins that compete with Botox.

Daewoong has recently constructed a facility in South Korea where it produces ABP-450 and Jeuveau, which is the same botulinum toxin complex as ABP-450. The manufacture of ABP-450 drug substance is based on the fermentation of Daewoong's C.botulinum cell line, followed by isolation and purification of the drug substance. Daewoong has received a United States patent for the production process. The drug substance production facility was purpose built and is in compliance with FDA and EMA cGMP requirements. We believe this facility will be sufficient to meet demand for ABP-450 for the foreseeable future.

# **Our Pipeline**

In July 2024, we announced a strategic reprioritization to pursue a 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product for all of the indications for which Botox is approved, other than the cosmetic uses (for which we do not hold development or commercialization rights). We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on the next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") meeting with the FDA in the second half of 2025 to review the results from the studies.

We have summarized below two important for ABP-450. migraine, Botox's highest revenue generating indication, and cervical dystonia, which AEON could elect to pursue in the event the Company fails to approval as a Botox biosimilar. The anticipated level of financing needed for our existing pipeline candidates is highly variable and difficult to project as the required analytical, and potentially clinical, studies, which are our primary cost drivers, will be largely based on the data generated and feedback from the FDA. As of the date of this Report, we expect to have sufficient cash to fund our operating plan into the fourth quarter of 2025. We are actively attempting to secure additional capital to fund our operations. However, we cannot assure you that we will be able to raise additional capital on commercially reasonable terms or at all. Any further development of ABP-450 for any indication, including the biosimilar pathway and any additional studies in cervical dystonia, will require additional funding, which may not be available to us on reasonable terms, or at all.

# Migraine

Migraine is a complex neurological condition characterized by recurrent episodes of headaches. Patients that suffer from migraine headaches experience symptoms including throbbing recurring pain, nausea, vomiting, dizziness and sensitivity to light, sound, touch and smell. Migraine attacks usually last between four and 72 hours. According to the *Global Burden of Disease Study* conducted in 2019, migraine is the second leading disability in the world. The development and course of migraines differs from patient to patient, where a subset of patients experience an increase in frequency over a period of months or years and may gradually evolve from low-frequency episodic migraine to high-frequency episodic migraine and then to chronic migraine.

Industry sources and published research estimate that approximately 15% of adults in the United States experience migraine or severe headache, which represents approximately 40 million people. An estimated 1 billion people worldwide suffer from migraines, making migraine the third most prevalent illness in the world. Using prevalence rates from various published

sources, we estimate that approximately 4.0 million people in the United States suffer from chronic migraines, defined as headache occurring on 15 or more days per month and eight or more migraines per month, with migraine defined as headache lasting for four or more hours per day, and that 9.4 million people in the United States live with episodic migraine, defined as headache occurring on 15 or fewer days per month and migraine occurring from six to 14 times per month.

Migraine treatment is broadly divided into two strategies: acute and prophylactic treatment. The primary goal of acute treatment is to provide relief from the pain and associated symptoms after a migraine attack has started. The primary goal of prophylactic, or preventative, treatment is to preemptively decrease the frequency, severity and duration of future migraine attacks. A key pathway for migraine and headache pain is the trigeminovascular input from the meningeal vessels. These nerves pass through the trigeminal ganglion and synapses on second-order neurons in the trigeminocervical complex, which then projects through the quintothalamic tract and, after decussating in the brain stem, form synapses with neurons in the thalamus. Disrupting pain stimulus to the trigeminocervical complex is one means of mitigating migraine headaches and botulinum toxin has pharmacological activity that can disrupt peripherical neuronal pain stimulus to the complex. Botulinum toxins are generally a third-line therapy in the prophylactic treatment of migraine patients. First- and second-line treatments to prevent migraine generally include the use of orally administered anti-epileptic, beta-blocker and tricyclic antidepressant pharmaceuticals, or the use of neuromodulation devices to stimulate the vagus nerve. Currently, the discontinuation rate for patients on existing oral preventive migraine medications is high due to poor tolerability and lack of efficacy. Migraine patients will typically progress to the third-line botulinum toxin therapy when first- and second-line therapies are not effective or not well-tolerated.

Botox is the only botulinum toxin approved by the FDA for prophylaxis of headaches in adult patients with chronic migraine and with a patented treatment protocol that designates a total dose of 155 units into 31 injection sites across seven areas of the head and neck. Botox is only approved for chronic migraine and there is no botulinum toxin approved for prevention of episodic migraine. Frequently reported adverse reactions following treatment with Botox for migraine include eyelid ptosis, commonly known as "drooping eyelid," neck pain and muscle weakness. Sales of Botox for chronic migraine were estimated to be \$691 million in 2019, and the use of Botox for chronic migraine increased from 2018 through the first quarter of 2021, with quarterly claims ranging from between 118,000 and 147,000 during this period. Such claims increased despite the introduction and presence of multiple CGRP (calcitonin gene-related peptide)- targeting medications during this period. We believe that as of March 2022, the majority of patients with chronic migraine who elected to switch treatment options chose Botox, with an estimated 65% of patients choosing Botox versus 35% choosing a CGRP. Another third-line treatment for migraine, referred to as CGRP-targeting medications, has recently been approved. CGRP is present in many organs in the body and when released around the nerves of the head, CGRP can cause inflammation and result in migraines.

CGRP-targeting medications seek to block the peptide itself in an effort to prevent migraine. CGRPs can target treatment of both chronic and episodic migraines, unlike Botox, which is used exclusively for treatment of chronic migraine. FDA-approved CGRPs include self-injectable monoclonal antibody formulations (Aimovig, Emgality, and Ajovy), an intravenous monoclonal antibody formulation (Vyepti) as well as oral formulations (Nurtec ODT and Qulipta). The use of CGRPs increased from 2018 through the second quarter of 2022, with quarterly claims ranging from between 875 and 547,000 during this period. Such claims stabilized in 2020, and Botox has returned to growth after a brief flat period we attribute to CGRP launches and COVID-19 challenges.

We are pursuing a 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product for all of the therapeutic indications for which Botox is approved. ABP-450 is a similar structure to OnabotulniumtoxinA (Botox) which was FDA- approved for the prevention of chronic migraine in 2010. The clinical trials for Botox involved close to 1,400 patients in two trials termed the PREEMPT trials. According to Botox, over five million Botox treatments have been used in over 850 thousand chronic migraine patients and is the top branded treatment for chronic migraine. ABP-450 has demonstrated similar results to OnabotuliniumtoxinA in other neurological conditions such as cervical dystonia and in glabellar lines (aesthetic use). Therefore, we believe ABP-450 has the potential to demonstrate a similar efficacy and safety profile as those seen with OnabotuliniumtoxinA with regards to prophylactic treatment for migraine. Further, there is no known physiological difference between episodic and chronic migraines, and we therefore believe a treatment that effectively addresses chronic migraine should similarly treat episodic migraine. This has been concluded in the studies of other migraine treatments, such as the injectable versions of the CGRP class of drugs, all of which have received both episodic and chronic migraine approvals. There has been extensive preclinical toxicology and other data developed by our licensing partner, Daewoong, and the aesthetic licensor of ABP-450, Evolus.

As of the date of this Report, we expect to have sufficient cash to fund our operating plan into the fourth quarter of 2025, including \$18.3 million in net proceeds related to a public offering in January 2025. For more information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources." We cannot assure you that we will be able to raise additional capital on commercially reasonable terms or at all. Any further development of ABP-450 for any indication, including the biosimilar pathway and any additional studies in cervical dystonia, will require additional funding, which may not be available to us on reasonable terms, or at all.

# Cervical Dystonia

Cervical dystonia, also known as spasmodic torticollis, is a neurological condition characterized by involuntary muscle contractions of the neck that may present as spasms, contractions or abnormal posture. It is a chronic condition with no cure, causing significant pain and challenges to mobility due to abnormal postures, and affecting quality of life and daily activities. Botulinum toxin is the standard of care for the treatment of cervical dystonia, helping to improve pain, posture, and disability.

We believe that ABP-450's mechanism of action has the potential to provide an effective treatment for patients suffering from cervical dystonia and, with a focused clinical program, may have the potential to provide an effective treatment for certain movement disorders, and broader muscle spasticity indications and labels. Botox, Dysport and Xeomin are currently approved by the FDA, and Daxxify's supplemental BLA was accepted by the FDA for the therapeutic treatment of cervical dystonia in adult patients to reduce the severity of abnormal head and neck pain. ABP-450 has a similar 900 kDa molecular weighting to Botox, which we believe will facilitate physician adoption of ABP-450 more rapidly and sustainably than other botulinum toxins that compete with therapeutic uses of Botox. We believe that this physician conversion will be enhanced by reimbursement advantages we intend to offer to payors and physicians that will differentiate the economics of using ABP-450 from Botox.

In August 2022, we completed our Phase 2 clinical study of ABP-450 for the treatment of cervical dystonia. This study enrolled 59 patients across approximately 20 sites in the United States. The study patients were randomized in a 1:1:1:1 ratio across four treatment arms: a low dose 150 units of ABP-450, a medium dose 250 units of ABP-450, a high dose 350 units of ABP-450, or placebo. A treatment cycle consisted of one treatment cycle. Due to the nature of the disease, dosing was tailored to the individual patient based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history. The safety and efficacy of each of the four arms was evaluated over a maximum of 20 weeks. At the completion of the Phase 2 clinical study, all patients, irrespective of treatment group, had the option to receive treatment with ABP-450 by rolling over into a 52-week open-label extension study, and 51 of the patients opted to do so.

The primary endpoint of the clinical study was to evaluate the safety and tolerability of the single treatment cycle of ABP-450. To do so, the study, among other things, assessed the proportion of patients who developed TEAEs during the first 20 weeks of a single treatment cycle at any of the administered doses of ABP-450. The secondary efficacy endpoints included evaluating (1) the mean difference of change from baseline to week four of each dosing cohort, as measured by the Total Toronto Western Spasmodic Torticollis Rating Scale, or TWSTRS, the standard scale for measuring the severity of cervical dystonia, (2) certain subscales of TWSTRS, (3) Patient Global Impression of Change, (4) Clinical Global Impression of Change, and (5) duration of effect as measured by the median time to loss of 80% peak treatment effect.

Topline data from the Phase 2 study, released in September 2022, confirmed that ABP-450 met the primary and a number of other key secondary endpoints, supporting the safety and efficacy of ABP-450 in reducing signs and symptoms associated with cervical dystonia. ABP-450 was generally safe and well-tolerated with (1) zero discontinuations due to TEAEs, (2) low rate of treatment-related TEAEs, (1) zero dysphagia cases in the 150 unit arm and low rate of dysphagia (11%) and muscle weakness (6.7%) overall, and (4) all treatment-related TEAEs were mild to moderate in severity and transient in nature.

We believe the ABP-450 efficacy results from our Phase 2 study are similar to those achieved by another company in the Phase 3 clinical trial it relied upon to submit a supplemental BLA application for the treatment of cervical dystonia using its toxin. ABP-450's efficacy results include: (1) TWSTRS at week four improved 14.01 points in the 150 unit arm, 11.28 points in the 250 unit arm, 9.92 points in the 350 unit arm, and 3.57 points in the placebo, showing a statistically significant change in the lower dose arms versus the placebo and clinically meaningful improvement (although not statistically significant) in all three arms; (2) Patient Global Impression of Change demonstrated statistically significant improvement in all three unit arms over the placebo; and (3) Clinical Global Impression of Change demonstrated statistically significant improvement in all three unit arms over the placebo. With respect to a few secondary endpoints, ABP-450 did not statistically separate from placebo, including in

the TWSTRS pain subscale in any of the arms, the TWSTRS severity subscale in the mid- and high-dose arms or the TWSTRS disability subscale in the high-dose arm.

The median duration of treatment effect was at least 20 weeks for all three treatment arms. We are currently preparing for the end of Phase 2 meetings with FDA and EMA. At this time, we cannot predict the cost of completing the development of ABP-450 for cervical dystonia. Given our current capital resources, we do not expect to continue development of ABP-450 in cervical dystonia, including the commencement of any Phase 3 clinical trials, unless and until we are able to raise additional capital to support those activities.

We acknowledge that others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program or the approvability or commercialization of the particular product candidate or product. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or product.

#### **Previous Development of our Botulinum Toxin**

The same botulinum toxin as ABP-450 has been approved for the cosmetic treatment of moderate to severe glabellar lines in the United States, the European Union and Canada, and a form of the botulinum toxin has been approved for the treatment of post-stroke upper limb spasticity in South Korea. Evolus markets and sells the same botulinum toxin as ABP-450 for the cosmetic treatment of moderate to severe glabellar lines under the brand name Jeuveau in the United States and under the brand name Nuceiva in the European Union and Canada, and Daewoong markets and sells its similar botulinum toxin under the brand name Nabota in South Korea. We believe that the Daewoong and Evolus studies related to the treatment of glabellar lines are relevant to the development of ABP-450 for therapeutic indications for several reasons, including that over 2,100 adults have been injected with a botulinum toxin that is identical or nearly identical to ABP-450 in the context of a clinical study program, generating significant safety, efficacy and non-inferiority data in the cosmetic setting.

# Daewoong Preclinical Toxicology Program

In accordance with international guidelines and in consultation with the FDA, Daewoong conducted a broad preclinical development program for ABP-450, including the study of dose concentrations contemplated for multiple therapeutic uses. The program included preclinical efficacy, safety, reproductive toxicity and single and repeat dose toxicity studies of ABP-450. While this program did not specifically contemplate the use of ABP-450 for migraine, cervical dystonia, or gastroparesis, we believe that the positive data derived from these preclinical studies will support the clinical development and anticipated future safety labeling of ABP-450 for migraine and cervical dystonia at all contemplated dose ranges. We will have to conduct additional toxicology studies to support the gastroparesis clinical program because it includes a new target organ.

#### Daewoong South Korean Clinical Development for Glabellar Lines

In South Korea, Daewoong conducted two clinical studies of Nabota, a form of the same botulinum toxin as ABP-450, to support its BLA for the cosmetic treatment of moderate to severe glabellar lines to the Korean Ministry of Food and Drug Safety, or MFDS, including one Phase 1 clinical study and one Phase 3 clinical study. Both studies were double-blind, randomized studies with an active control, Botox. Each study compared 20 units of Nabota with 20 units of Botox, injected into each of five target sites in the glabellar region of adult subjects with moderate to severe glabellar lines.

Nabota was approved by the MFDS for marketing on November 29, 2013 for the treatment of glabellar lines. The Nabota formulation, which was used in the early South Korean studies and which was commercialized by Daewoong, is slightly different than the formulation used in the studies sponsored by Evolus. The original Daewoong product was lyophilized and used a different human serum albumin that had not been approved by the FDA or EMA. With the approval of the Evolus vacuum dried product, Jeuveau, Daewoong has harmonized its product to be the same as the Evolus product and the same as the product that will be used in the clinical studies sponsored by us.

#### Evolus Clinical Development for Glabellar Lines

In 2014, Evolus initiated a comprehensive five-study clinical development program for Jeuveau, which consists of the same botulinum toxin complex as ABP-450, in the United States, the European Union and Canada to meet the regulatory requirements for a BLA in the United States, marketing authorization application, or MAA, in the European Union, and NDS, in Canada, for the cosmetic treatment of moderate to severe glabellar lines. The Evolus development program included three multicenter, randomized, double-blinded, controlled, single dose Phase 3 clinical studies and two open-label, multiple dose, long-term Phase 2 clinical studies. In each of the studies related to Jeuveau for the treatment of glabellar lines, the Jeuveau treatment group showed superiority over the placebo group and, where Botox was included as an active control, the Jeuveau treatment group was determined to be non-inferior to Botox. Between September 2014 and August 2016, over 2,100 adult male and female subjects with moderate to severe glabellar lines at maximum frown participated in this program. Jeuveau was approved for the cosmetic treatment of moderate to severe glabellar lines by the FDA in February 2019, and the same botulinum toxin was approved under the brand name Nuceiva by Health Canada in August 2018 and by the European Commission in September 2019.

# Daewoong South Korean Clinical Development for Post-Stroke Upper Limb Spasticity

Daewoong has conducted a post-stroke upper-limb spasticity Phase 3 clinical study in South Korea. It was a randomized, double-blind, multi-center, active drug controlled, Phase 3 clinical study to compare the safety and efficacy of up to 360 units of Nabota to Botox. Nabota was found to be non-inferior to Botox in this study. The result of this study was the basis for registration and approval of Nabota with the MFDS for the post-stroke upper limb spasticity indication in South Korea.

Patients diagnosed with a stroke at least six weeks prior to the start date of the study and found to be eligible based on the screening test result were randomized to either Nabota or Botox. Treatment consisted of intramuscular injections of up to 360 units to the wrist flexor, elbow flexor, finger flexor or thumb-in-palm; the total dose depended on the existence and severity of spasticity. In order to assess efficacy and safety after the treatment, follow-up visits were performed at four, eight and 12 weeks.

The primary endpoint compared the evaluations of the changes in muscle tension values as measured by the Modified Ashworth Scale, or MAS, scores of wrist flexors at four weeks after the injection compared to the scores before treatment. The changes in the wrist flexor MAS assessed by the investigator at four weeks after treatment compared to the baseline in the per protocol analysis group for the primary efficacy assessment were -1.44±0.72 points and -1.46±0.77 points in the Nabota and Botox group, respectively. Both groups demonstrated statistically significant decreases (p<0.0001) in muscle tension as measured on the MAS. The difference between the Nabota and Botox groups was 0.0129, with a 95% confidence interval (-0.2062, 0.2319). Since the upper limit of the 97.5% one-sided confidence interval of the difference in changes was 0.2319, Nabota was found to be non-inferior to Botox. As a secondary endpoint, the average change in muscle tension as measured on the MAS of both groups as compared to baseline, when measured at week 8 and week 12, remained statistically significant at all points in time.

After administration of the treatment, adverse events occurred in 19.6% of the subjects in the Nabota group and 19.4% of the subjects in the Botox group. Adverse drug reactions occurred in 3.1% of the subjects in the Nabota group and in 4.1% of the subjects in the Botox group. There was one serious adverse event, a radius fracture that occurred in the Nabota group, which was assessed as not study drug-related. Botulinum neutralizing antibody testing was conducted using mouse bio-assay, and there were no "positive" subjects found in either group. Nabota is now approved for post-stroke upper limb spasticity in South Korea.

# Daewoong South Korean Clinical Development for Blepharospasm

Daewoong has conducted a blepharospasm Phase 2/3 comparator study in South Korea. It was a randomized, double-blind, multi-center, active drug controlled, Phase 3 clinical study to compare the safety and efficacy of Nabota to Botox. This study was the basis for registration and approval of Nabota with the MFDS for the blepharospasm indication in South Korea. Patients diagnosed with facial spasms prior to the start date of the study and found to be eligible based on the screening test result were randomized to either Nabota or Botox. Treatment consisted of intramuscular injections into the medial and lateral pretarsal orbicularis oculi of the upper lid and lateral pretarsal orbicularis oculi of the lower lid of up to 46.88± 9.46 units of Nabota or 46.86± 9.46 units of Botox; the total dose depended on the severity of the spasms. In order to assess efficacy and safety after the treatment, follow-up visits were performed at four, eight and 12 weeks.

# **Our Strategy**

Our goal is to change patients' lives by enhancing the therapeutic botulinum toxin treatment paradigm for patients suffering from debilitating conditions. To achieve this goal, we plan to:

- Develop and Seek Regulatory Approval for ABP-450 as a Biosimilar to Botox. Our primary focus is on the development of ABP-450 as a biosimilar to Botox. We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on the next steps to develop our Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies. As of the date of this Report, we expect to have sufficient cash to fund our operating plan into the fourth quarter of 2025, including \$18.3 million in net proceeds related to a public offering in January 2025. For more information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources." We are actively attempting to secure additional capital to fund our operations. However, we cannot assure you that we will be able to raise additional capital on commercially reasonable terms or at all. Any further development of ABP-450 for any indication, including the biosimilar pathway beyond the planned BPD meeting in 2025, will require additional funding, which may not be available to us on reasonable terms, or at all.
- Expand the Field of Therapeutic Applications for Botulinum Toxins. We believe ABP-450 can be developed to address a broad range of debilitating diseases where existing treatment options do not exist, have proven to be inadequate or are poorly tolerated. To identify target indications for development, we employ a rigorous portfolio screening process that evaluates strategic fit, potential commercial opportunity and clinical and regulatory development risks. We initially identified over 230 potential therapeutic uses for botulinum toxins and plan to continue to evaluate therapeutic use for chronic diseases where there is no approved botulinum toxin therapy. For example, we are exploring the use of ABP-450 as a potential treatment for neuropsychiatric disorders and initiated a preclinical study of ABP-450 in animal models to characterize the safety and toxicology prior to entering human studies.
- Enhance the Economics of Botulinum Toxin Treatments to Drive Value for Payors and Physicians. We plan to pursue approval of an original BLA that exclusively contemplates therapeutic indications for ABP-450. If we obtain an original BLA for therapeutic indications of ABP-450, we would have the pricing flexibility to enhance rebates to payors and/or providers to improve reimbursement coverage for therapeutic indications, which we believe will provide better access to botulinum toxin therapy to a broader population of patients. We believe this would also enable physicians to receive consistent, favorable reimbursement when they choose to use ABP-450 for their therapeutic botulinum toxin treatments.
- Participate in the Growing Therapeutic Botulinum Toxin Market by Optimizing Value of ABP-450. The global therapeutic botulinum toxin market is expected to continue to grow, and we believe that we can significantly expand the market through our target indications, proposed treatment protocols and anticipated pricing. The current market leader commanded approximately 95% of the United States therapeutic market share for botulinum toxins in 2019, driven primarily by its historical investment into development programs such as chronic migraine and overactive bladder. We have exclusive development and distribution rights for therapeutic indications of ABP-450 in the United States, Canada, the European Union, the United Kingdom and certain other international territories. We plan to develop and pursue approval of ABP-450 for a variety of indications in major markets, beginning with the United States, where we intend to build a focused, specialized commercial organization to launch the product. Where appropriate outside the United States, we may use strategic collaborations and partnerships to accelerate the development and maximize the commercial potential of our programs.

#### **Our Competitive Strengths**

We believe the successful pursuit of our strategy will be driven by the following competitive strengths:

- Well-Established 900 kDa Botulinum Toxin Complex. ABP-450 is the same botulinum toxin complex that has been approved by regulatory authorities in the United States, the European Union, and Canada for a cosmetic indication. To receive these global approvals, Daewoong and Evolus have completed rigorous clinical development programs using Botox as an active comparator and consistently showed that ABP-450 was non-inferior to Botox at doses ranging from 20 units to 360 units. While we have not yet demonstrated non-inferiority of ABP-450 to Botox with respect to therapeutic uses, we expect to design our studies, if successful, to demonstrate that one unit of ABP-450 will produce a substantially similar effect as one unit of Botox. ABP-450 has a similar 900 kDa molecular weighting to Botox, which we believe will facilitate physician adoption of ABP-450 more rapidly and sustainably than other botulinum toxins that compete with therapeutic uses of Botox. For example, Dysport and Xeomin have molecular weightings of 400 kDa and 150 kDa, respectively, and differences in molecular weightings can result in different clinical outcomes and require physicians to utilize different dilution ratios and injection techniques than they would use with Botox.
- ABP-450 Has Potential Application Across a Broad Range of Indications. ABP-450 is a single product candidate that we believe can produce a diverse product development platform spanning a broad spectrum of indications. We believe that our cervical dystonia program has an established regulatory pathway that, if successful, would allow us to participate in an established market. Our migraine program, if successful, represents an important expansion of treatments available in the estimated \$18.5 billion episodic migraine market, combined with a streamlined injection protocol designed to enhance safety and tolerability for all indicated migraine patients. Our gastroparesis program, if successful, would be a novel indication for botulinum toxins in a market characterized by high unmet need and low competitive intensity. We have identified six additional, undisclosed therapeutic indications that we intend to pursue that offer similar market opportunities.
- Differentiated Business Model Designed to Deliver Enhanced Value to Payors and Physicians. We believe our exclusive focus on developing ABP-450 for therapeutic indications provides us with a competitive advantage against current and known prospective botulinum toxin competitors. We believe this focus will enable us to pursue an original BLA dedicated to therapeutic uses of ABP-450 that, if obtained, would allow physicians to receive consistent and favorable reimbursement from payors, while also providing us with the flexibility to provide economic incentives, including rebates, to payors and/or providers. Market competitors that receive marketing approval for their botulinum toxin products have traditionally obtained an original BLA for their initial indication, with follow-on supplemental BLAs as they expand their product labels to include cosmetic and therapeutic indications. As a consequence of that structure, the ASPs for therapeutic reimbursement are negatively affected by promotional activity associated with cosmetic pricing. If we receive an original BLA, we believe that we will not have a negative pricing influence from lower-priced cosmetic indications, which should allow us to uniquely manage our ASP in a manner that enhances value to payors and physicians.
- Management Team with Significant and Relevant Experience and Expertise in the Therapeutic Use of Botulinum Toxins. Our management team has extensive experience in the botulinum toxin market in multiple therapeutic areas, in the development, market launch and commercialization of major medical products, in the execution and integration of business development transactions, and a deep understanding of the regulatory environment of the healthcare markets. Our management team also has a proven history of raising financing in support of our botulinum toxin product candidates, including raising \$197 million for investment in AEON since 2019, inclusive of the \$20 million gross proceeds related to a public offering in January 2025. For more information, see discussion of the offering within

"Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

# Manufacturing

Daewoong is our sole supplier of ABP-450. Daewoong has over 70 years of experience manufacturing pharmaceutical products and is one of the largest pharmaceutical drug companies in South Korea. Daewoong recently constructed a facility in South Korea for the purposes of producing ABP-450 drug product, which was purpose-built to comply with FDA and EMA regulations. We believe this facility will be sufficient to meet demand for ABP-450 for the foreseeable future. The FDA conducted a cGMP and pre-approval inspection of the facility from November 8 to November 17, 2017. The United Kingdom Medicines and Healthcare Products Regulatory Agency also completed an inspection of the manufacturing facility in February 2018 in connection with Evolus' MAA for Jeuveau. Evolus' FDA approval of Jeuveau in February 2019 included approval to manufacture Jeuveau at Daewoong's facility. A separate pre-licensure inspection may be required for any BLA we submit for any of our product candidates and we believe that Daewoong's manufacturing facility is, and will remain, compliant with FDA and EMA cGMP requirements.

While Jeuveau and ABP-450 are both manufactured by Daewoong, both we and Evolus retain separate, independent oversight rights related to Daewoong's compliance with cGMP, standards specified by good manufacturing practice, and all other applicable regulatory guidelines and requirements. Evolus retains independent oversight and responsibility for the quality and pharmacovigilance of Jeuveau under its BLA and related international approvals; similarly, we retain independent oversight and responsibility for the quality and pharmacovigilance of ABP-450 under our original BLA, if approved.

Daewoong manufactures the ABP-450 drug substance in a separate facility on the same campus. The manufacture of ABP-450 drug substance is based on the fermentation of Daewoong's C. botulinum cell line, followed by isolation and purification of the drug substance. Daewoong has received a United States patent for the production process.

Daewoong is a defendant in several lawsuits brought by Medytox, alleging, among other things, that Daewoong stole Medytox's botulinum toxin bacterial strain and misappropriated trade secrets of Medytox, including those used by Daewoong to manufacture ABP-450. Daewoong is also a respondent to a complaint made by Medytox and Allergan to the United States ITC, containing substantially similar allegations regarding the alleged theft of Medytox's botulinum toxin bacterial strain and misappropriation of Medytox's trade secrets, which is currently on appeal to the United States Court of Appeals for the Federal Circuit. We were also a defendant in the lawsuit brought by Medytox in the United States District Court for the Central District of California asserting allegations that are substantially similar to those in the Korea Litigation. In June 2021, we settled all outstanding claims with Medytox and entered into a non-exclusive, royalty-bearing, irrevocable license that permits us to commercialize and manufacture ABP-450. See "Risk Factors — Risks Related to Our Reliance on Third Parties — A material breach by us of the terms of our license and settlement agreement with Medytox, Inc. could have a material adverse effect on our business."

# **Daewoong License and Supply Agreement**

On December 20, 2019, we entered into the Daewoong Agreement, pursuant to which Daewoong agreed to manufacture and supply ABP-450 and grant us an exclusive license for therapeutic indications to import, distribute, promote, market, develop, offer for sale, and otherwise commercialize or exploit ABP-450 in the United States and its territories and possessions, the European Union, the United Kingdom, Canada, Australia, Russia, the Commonwealth of Independent States, and South Africa, which we refer to collectively as the "covered territories."

Daewoong has agreed to exclusively supply us with, and we have agreed to exclusively obtain from Daewoong all of our requirements of ABP-450 at agreed-upon transfer prices, with no milestone or royalty payments and no minimum purchase requirements. Daewoong is responsible for all costs related to the manufacturing of ABP-450, including costs related to the operation and upkeep of its manufacturing facility, and we are responsible for all costs related to obtaining and maintaining regulatory approval, including clinical expenses, and commercialization of ABP-450. We are obligated to use commercially reasonable efforts to: (i) obtain all regulatory approvals necessary for ABP-450 to be marketed and commercialized in the covered territories for therapeutic indications and (ii) commercialize ABP-450 in the covered territories for therapeutic indications. During the term of the Daewoong Agreement, we cannot purchase, sell or distribute any injectable botulinum toxin

that is launched in the covered territories after the effective date of the Daewoong Agreement other than ABP-450 in the covered territories or sell ABP-450 outside a covered territory.

Under the Daewoong Agreement, Daewoong grants us an exclusive, irrevocable, sub-licensable, assignable, fully paid-up license during the term to use Daewoong's trademarks to Nabota in our commercialization and related obligations surrounding marketing authorizations of ABP-450 for therapeutic uses in the covered territories.

The initial term of the Daewoong Agreement is from December 20, 2019 to the later of (i) the fifth anniversary of the grant of approval from the relevant governmental authority necessary to market and sell ABP-450 in the covered territories or (ii) December 20, 2029, and automatically renews for unlimited additional three-year terms thereafter, provided the Daewoong Agreement is not earlier terminated. The Daewoong Agreement will terminate upon written notice (A) by either us or Daewoong upon a continuing default that remains uncured within 90 days (or 30 days for a payment default) by the other party, or (B) immediately upon written notice if the breach is not capable of cure; (C) upon any of the following without notice: (i) our bankruptcy, insolvency or a petition for either, (ii) our assignment of our business or the Daewoong Agreement in whole or in part for the benefit of creditors, (iii) appointment of a receiver over any of our assets not vacated in sixty days, or (iv) filing of any other petition based upon our alleged bankruptcy or insolvency not dismissed within ninety days, or (D) our failure to commercialize or conduct clinical studies related to ABP-450 for a six month period. In the event the license is terminated for either of the reasons listed in (C) or (D) of the foregoing sentence, Daewoong will have the right to buy our intellectual property and data, which represents the majority of AEON's valuable assets, for one dollar (\$1.00), which right will terminate in the event Daewoong sells more than fifty percent (50%) of its ownership (inclusive of shares received in connection with the conversion of the Convertible Notes).

We will be the sole owner of any marketing authorization we pursue related to therapeutic indications of ABP-450 in a covered territory. This will include ownership of any BLA that we may submit to the FDA, MAA that we may submit to the EMA, NDS that we may submit to Health Canada, and any other approvals we receive in a covered territory. However, if we do not renew the Daewoong Agreement or upon termination of the Daewoong Agreement due to a breach by us, we are obligated to transfer our rights to Daewoong.

The Daewoong Agreement also provides that Daewoong will indemnify us for any losses arising out of Daewoong's willful misconduct or gross negligence in performing its obligations under the agreement, Daewoong's breach of the agreement, or any allegation that ABP-450 or Daewoong's trademark infringes or misappropriates the rights of a third party, except, in each case, as a result of our willful misconduct or gross negligence. We have agreed to indemnify Daewoong for any losses arising out of our willful misconduct or gross negligence in performing our obligations under the agreement, or our breach of the agreement, except, in each case, as a result of Daewoong's willful misconduct or gross negligence.

For more information associated with this and other risks, please see "Risk Factors — Risks Related to Intellectual Property and Risks Related to Our Reliance on Third Parties." Following the settlement between us and Medytox, on July 29, 2022, we amended the Daewoong Agreement and agreed to release any potential indemnification claims associated with the Company's settlement with Medytox.

#### **Intellectual Property**

Our success depends, in large part, on our ability to obtain and maintain intellectual property protection related to our product candidate in our proposed therapeutic indications, novel methods of use, and other know-how and for future product candidates. Our ability to operate without infringing on the proprietary or intellectual property rights of others and to prevent others from infringing our proprietary and intellectual property rights will be important to our performance. We protect, and will continue to protect, our proprietary technology and methods by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions, methods of use, and improvements that are important to the development and implementation of our business as well as by maintaining trade secret protection and through other confidentiality procedures. In November 2023, the Company was issued a patent for its treatment paradigm (U.S. Patent No. 11,826,405) involving fewer injections than the current botulinum toxin treatment option for migraine. Although we own pending United States patent applications related to ABP-450, with the exception of our treatment paradigm patent, such pending applications have not issued as a patent, and we do not otherwise own or in-license any issued patents in or outside the United States.

Under the Daewoong Agreement, Daewoong agreed to exclusively manufacture and supply ABP-450 to us and grant us an exclusive license for therapeutic indications to import, distribute, promote, market, develop, offer for sale and otherwise commercialize and exploit ABP-450 in the covered territories. Daewoong has a United States patent on its proprietary botulinum toxin manufacturing process for ABP-450. At this time, we own one issued patent, six pending Patent Cooperation Treaty international patent applications, no pending United States provisional patents and six pending United States nonprovisional patent applications related to ABP-450, including certain novel methods and protocols of injecting for the treatment of migraine and gastroparesis. If issued, these patents would expire in 2040. We also rely on know-how, copyright, trademarks, and trade secret laws to protect our proprietary advancements and competitive advantage. Such protection is also maintained using confidentiality agreements.

It is possible that our current pending patents, or patents which we may later acquire or license may be successfully challenged or invalidated in whole or in part. It is also possible that we may not obtain issued patents from our pending patent applications or other inventions we seek to protect. Due to uncertainties inherent in prosecuting patent applications, it is possible that our pending patent applications will be rejected. It is also possible that we may develop proprietary products or technologies in the future that are not patentable or that the patents of others will limit or altogether preclude our ability to do business. In addition, any patent issued to us may provide us with little or no competitive advantage, in which case we may abandon such patent or license it to another entity. Additionally, we own trademark applications in the United States for AEON & Design, AEON BIOPHARMA & Design and AEON BIOPHARMA, which have been refused registration at the Trademark Office on the grounds of an alleged likelihood of confusion with prior registrations for AEON and EON owed by a third party for nutritional supplements. We have filed a petition to cancel the third-party marks with the U.S. Trademark Trial and Appeal Board.

In addition to our reliance on patent protection for ABP-450 and future product candidates, we also rely on our and our licensors' trade secrets, know-how, confidentiality agreements and continuing technological innovation to develop and maintain our competitive position. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, these agreements may be breached and we may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived of by the individual during the course of employment, and which relate to or are reasonably capable of being used in our current or planned business or R&D are our exclusive property. However, such agreements and any security policies may be breached and we may not have adequate remedies for such breaches. For more information, see "Risk Factors — Risks Related to Intellectual Property."

#### Competition

The pharmaceutical industry is highly competitive and requires an ongoing, extensive search for technological innovation. It also requires, among other things, the ability to effectively discover, develop, test and obtain regulatory approvals for novel products, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical professionals. Numerous companies are engaged in the development, manufacture and marketing of products competitive with those that we are developing. Many of our competitors have greater resources than we have. This enables them, among other things, to leverage their financial resources to make greater R&D, marketing and promotion investments than us. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors.

As more companies develop new intellectual property in our markets, the possibility of a competitor acquiring patent or other rights that may limit our products or potential products increases, which could lead to litigation. In addition to product development, testing, approval and promotion, other competitive factors in the pharmaceutical industry include industry consolidation, product quality and price, product technology, reputation, customer service and access to technical information.

We are currently focusing our clinical efforts on the use of botulinum toxins to treat migraine, cervical dystonia, and gastroparesis and expect to pursue indications to treat other therapeutic conditions. We expect to compete directly with other injectable botulinum toxins and other pharmaceuticals that are currently utilized and being developed for each of these disease states.

#### Injectable Botulinum Toxins

Our primary competitors for ABP-450 in the injectable botulinum toxin pharmaceutical market for therapeutic use are Botox, Dysport, Xeomin, Myobloc, a type-B botulinum toxin serotype marketed by U.S. WorldMeds, and Revance's botulinum toxin, Daxxify. Revance has entered into a collaboration and license agreement with Viatris Inc., to develop and commercialize a biosimilar to Botox. Each of Botox, Dysport, Xeomin, Myobloc and Daxxify are approved by the FDA for the treatment of cervical dystonia. Botox is currently the only botulinum toxin approved for the treatment of chronic migraine, although we believe that a clinical study is being conducted to evaluate Dysport for the treatment of chronic migraine. There are no approved botulinum toxins approved for the treatment of gastroparesis and, to our knowledge, there are no active clinical studies evaluating the potential of another neurotoxin to treat gastroparesis.

We are aware of competing botulinum toxins currently being developed or commercialized in the United States, the European Union, Asia, South America, and other markets. While some of these products may not meet United States regulatory standards, the companies operating in these markets may be able to produce products at a lower cost than United States and European manufacturers. In addition to the injectable botulinum toxin dose forms, we are aware that other companies are developing topical botulinum toxins for therapeutic indications.

#### Preventative Treatment of Migraine

Beta Blockers, Anti-Epileptics, and Triptans

Botox is approved for the preventative treatment of chronic migraine and certain other agents are used as first-and second-line treatments for the prevention of migraine, including triptans, beta blockers, and anti-epileptics.

Calcitonin Gene-Related Peptide (CGRP)

We will also face competition in our target therapeutic markets from companies that provide treatment options with other pharmaceutical or non-pharmaceutical products. For the preventative treatment of chronic migraine, we will face competition from CGRP agonists, including Aimovig (erenumab) marketed by Amgen Inc., Ajovy (fremenezumab) marketed by Teva Pharmaceutical Industries Ltd., and Emgality (galcenezumab) marketed by Eli Lilly and Company. Each of Aimovig, Ajovy and Emgality are self-administered by a monthly subcutaneous injection. In 2020, Vyepti (eptinezumab) marketed by Lundbeck A/S was approved for the prevention of migraine and is administered every 3 months by intravenous infusion. In addition, Qulipta (atogepant) marketed by AbbVie and Nurtec ODT (rimegepant) marketed by Pfizer Inc. have recently been approved for the prevention of migraine via once-daily, orally administered products in 2021 and 2023, respectively. The FDA has also accepted a New Drug Application for vazegepant, marketed by Pfizer Inc., to be used as an intranasal formulation for both the acute treatment and prevention of migraine. If approved, this therapy will be commercially available for the treatment of migraine prior to ABP-450. Notably, initial positive data has been published studying the reduction in migraine days when a botulinum toxin is used in combination with CGRP, suggesting that combination therapy could provide further reduction in MMD than either botulinum toxin or CGRPs alone.

#### **Other Treatments**

We will also face competition in our target therapeutic markets from companies that provide treatment options with other pharmaceutical or non-pharmaceutical products. For the treatment of cervical dystonia, in addition to other injectable botulinum toxins, we will face competition from orally administered anticholinergic, GABA receptor agonist, benzodiazepine, dopaminergic and anticonvulsant pharmaceuticals. For the treatment of gastroparesis, we will face competition from prokinetic agents, including REGLAN (IV administered metoclopramide) and Gimoti (nasal spray metoclopramide), which are the only medications currently approved by FDA for the treatment of gastroparesis.

#### **Government Regulation**

We operate in a highly regulated industry that is subject to significant federal, state, local and foreign regulation. Our business has been, and will continue to be, subject to a variety of laws including the Federal Food, Drug and Cosmetic Act, or FFDCA, and the Public Health Service Act, or PHS Act, among others. Biological products or "biologics," which are the focus of our business, are subject to regulation under the FFDCA and PHS Act. Our products, if approved, will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered and licensed facilities in compliance with cGMP for biologics. Among other things, biologics require clinical studies to demonstrate product safety and efficacy (i.e., that the product is safe, pure and potent), and the submission and approval of a BLA for marketing authorization. Also, various federal and state laws govern the R&D, testing, investigation, manufacture, storage, recordkeeping, regulatory approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of these products. Failure to comply with applicable United States requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending license or marketing applications, warning letters, enforcement actions, import alerts or detentions, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of approval, injunctions, fines, civil penalties and criminal prosecution.

# United States Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals under the Animal Welfare Act and its implementing regulations, or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the proposed biologic for its intended use, according to the FDA's regulations, commonly referred to as good clinical practices, or GCPs, and any additional requirements including those for the protection of human research subjects and their health and other personal information;
- preparation and submission to the FDA of a BLA for marketing approval which contains, among other things, data supporting the safety and effectiveness of the biologic, and data on the chemistry, manufacturing, and controls, or CMC, of the product that support the identity, strength, quality, purity, and potency of the biologic that will be produced;
- satisfactory completion of an FDA pre-licensure inspection of the manufacturing facility or facilities where the biologic is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality, purity, and potency;
- potential FDA audits of the nonclinical study and clinical study sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA.

#### Nonclinical Studies

Biological product development in the United States typically involves nonclinical or "preclinical" (e.g., laboratory or animal) testing. Nonclinical tests often include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with applicable federal regulations and requirements including GLPs, among other requirements. The results of initial nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, any relevant prior clinical experience, and a proposed clinical study protocol.

Additional nonclinical testing, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted and generally must be included in the BLA.

#### Clinical Studies

Prior to beginning the first clinical study with a product candidate, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical and clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. For clinical studies in the United States or otherwise regulated by the FDA, a 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not raised questions or concerns relating to the IND and placed the IND on clinical hold within this 30-day period, the clinical study proposed in the IND may begin. If the FDA does place the IND on clinical hold, the IND sponsor must resolve any outstanding concerns to the FDA's satisfaction before the clinical study can begin.

Clinical studies for a product candidate may involve the administration of the investigational biologic to subjects under the supervision of one or more qualified investigators. Clinical studies must be conducted pursuant to an IND and in compliance with state and federal regulations and GCPs, an international standard meant to protect the rights and health of subjects and to define the roles of clinical study sponsors, administrators, and monitors, as well as under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on United States subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other requirements or sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical study subjects. The clinical study protocol, any protocol amendments, and informed consent information for subjects in clinical studies must also be submitted to an IRB for approval. An IRB may require the clinical study at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions before approving the study for initiation. The IRB also approves the form and content of the informed consent form that must be signed by each clinical study subject or his or her legal representative, and the IRB must monitor the clinical study until completed. There are also requirements governing the reporting of ongoing preclinical and clinical studies and clinical study results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product candidate is initially introduced into a limited population of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion. In the case of some products for some diseases or when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the disease or condition for which the product candidate is intended to gain an early indication of its effectiveness.
- Phase 2. The product candidate is evaluated in a limited patient population, but larger than in Phase 1, to identify possible adverse events and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications, and to assess dosage tolerance, optimal dosage, and dosing schedule.
- Phase 3. Clinical studies are undertaken to further evaluate dosage and provide substantial evidence of clinical efficacy and data supporting safety in an expanded patient population, such as several hundred to several thousand subjects, at geographically dispersed clinical study sites. Diversity of subject populations also has become an area of increased focus, supported by FDA and legislative actions to establish requirements for diversity action plans to ensure inclusion of underrepresented racial and ethnic populations in Phase 3 clinical trials. Phase 3 clinical studies are typically conducted when Phase 2 clinical studies demonstrate that a dose range of the

product candidate is effective and has an acceptable safety profile. These studies typically have at least two groups of patients who, in a blinded fashion, receive either the product or a placebo.

- Phase 3 clinical studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical studies are required by the FDA for approval of a BLA.
- Phase 4. In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the product. These clinical studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. Such post-approval studies are sometimes referred to as "Phase 4" clinical studies.

Concurrently with clinical studies, companies may complete additional nonclinical studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs and also CMC requirements that are approved as part of the BLA. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the finished product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug product candidate does not undergo unacceptable deterioration over its shelf life.

# Biological License Applications (BLAs)

Pursuant to the PHS Act Section 351, in order to market a biological product, an entity must submit and receive approval of a BLA based on a demonstration that (a) the biological product that is the subject of the application is safe, pure, and potent; and (b) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent. When an FDA application is approved in the first instance, it is an "original BLA" which is assigned a BLA number by the FDA.

An approved "original" BLA may be supplemented (amended) to incorporate changes. Specifically, FDA regulations state that an applicant holding a BLA "shall submit a supplement," and receive FDA approval of a supplement, before implementing the addition of a new indication, and other changes that may have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product. When approved, the supplement incorporates the changes into the BLA under the original BLA number. It is also possible that an applicant may, in some cases, submit a separate original application instead of a supplement based on intended changes and discussions with FDA. However, if an entity does not hold a BLA, a supplement would not be an option.

A BLA holder is legally responsible for all regulatory obligations associated with the BLA, including each supplement thereto, and is the only party that would be authorized to submit a supplement. If an entity does not hold a BLA, it does not hold an application to supplement and would generally need to submit an original BLA. Companies typically submit a BLA sometime after they have developed data necessary to support the safety, purity, and potency (safety and effectiveness) for labeled indication(s) and method(s) of use. We expect to submit our original BLA after such data has been developed. From an FDA regulatory perspective, we believe we will be eligible to submit an original BLA for our product candidate (ABP-450) because we do not hold a BLA for ABP-450 that we could supplement. As such, an original BLA would be the appropriate option for our first BLA submission. For clarity, although we will not physically manufacture products (the product will be produced by Daewoong), FDA recognizes that separate parties can serve as a BLA holder for a product (responsible for ensuring regulatory compliance) and the physical manufacturer that will produce for a BLA holder pursuant to contract (i.e., a "contract manufacturer"). Thus, we plan to submit, and ultimately hold, an approved original BLA for the ABP-450 product that is contract manufactured by Daewoong.

We are aware that a separate legal entity — Evolus — markets a product called Jeuveau (prabotulinumtoxinA-xvfs), also manufactured by Daewoong, which is very similar to our ABP-450 product, but has been approved for cosmetic indications. We are developing ABP-450 for therapeutic (not cosmetic) indications, will be marketing under a different trade name, and may

potentially incorporate other changes. Evolus and AEON are distinct legal entities, will maintain their own manufacturing arrangements with Daewoong, and will market products with different indications and trade names, at minimum. As such, we believe it is appropriate that we maintain separate and distinct regulatory obligations for ABP-450, which would be accomplished by submitting and receiving approval for an original BLA.

The form of BLA approval is pertinent because payors will generally consider the pricing for all products falling under the same BLA together when calculating reimbursement rates. Notably, Medicare Part B payments for prescription drugs factor in prices for all versions of a drug, even when certain versions of the drug may be used primarily in situations that are not covered by the program (such as cosmetic applications). Centers for Medicare & Medicaid Services, or CMS, has interpreted the Medicare statute to require that: (1) all versions of a product listed under the same BLA must be considered the same drug or biological, for payments made under Section 1847A of the Social Security Act, and (2) for a product marketed under the same approval number, labeling that indicates that a version may be used primarily when the drug is not covered under Part B (e.g., the version is for self-administration only, or for cosmetic use) cannot be used as a basis to exclude that version from a payment amount calculation.

In the event we are not able to obtain an original BLA, we may not be able to ensure the consistent pricing that we believe an original BLA would offer, and the ASP of our products could be adversely affected.

#### **BLA Submission and Marketing Approval**

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA must include the results of all nonclinical, clinical and other testing, and a compilation of data relating to the product's CMCs. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application fee, and the sponsor of an approved BLA is also subject to annual program fees.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review, and such decision could result in a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. The FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. Priority review designation will direct overall attention and resources to the evaluation of applications for products that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA reviews a BLA to determine, among other things, whether a product candidate is safe and effective for its intended use, and whether the facility in which it is manufactured, processed, packed and held meets regulatory standards designed to assure and preserve the product's identity, safety, strength, potency, quality, and purity. The FDA may also refer applications for novel biologics products or biologics products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee but often follows some or all of its recommendations.

In addition to the above, under the Pediatric Research Equity Act, a BLA applicant, absent a deferment or waiver, must develop a pediatric development plan and, potentially, conduct pediatric studies prior to submission of the BLA.

Pre-licensure inspections are often conducted at one or more clinical study sites and may be conducted at nonclinical testing sites as well. Additionally, the FDA will inspect the facility or the facilities at which the biological product is manufactured prior to approval. The FDA will not approve the BLA unless it determines that compliance with cGMP is satisfactory. Manufacturers of biologics also must comply with the FDA's general biological product standards and approved CMC requirements.

After the FDA evaluates the BLA and information from any pre-licensure inspections or other data sources, it issues either an approval letter or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing, including additional large-scale clinical testing or information in order for the FDA to

reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to the goal of reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the finished biological product within the United States with specific labeling (e.g., prescribing information) for specific indications. As a condition of BLA approval, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy and may impose other conditions, including labeling restrictions, which can materially affect the product's potential market and profitability. For example, the FDA may approve the BLA with REMS to ensure the benefits of the product continue to outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems or safety issues are identified following initial marketing. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. Changes to some of the conditions established in an approved application, including changes in indications, labeling, ingredients or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented.

A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

#### **Expedited Development and Review Programs**

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy designation, and accelerated approval.

A product is eligible for priority review, or review within a six-month timeframe from the date a complete BLA is accepted for filing, if it has the potential to provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the BLA.

In addition, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a product is so designated, the FDA will take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, products that may fulfill an unmet medical need and are studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on an intermediate clinical endpoint that can

be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled Phase 4 post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Failure to confirm efficacy in post-marketing studies or otherwise comply with the conditions of accelerated approval could result in withdrawal of approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review and approval will not be shortened. Furthermore, priority review, fast track designation, and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

# Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, restrictions on import or export, complete withdrawal
  of the product from the market or product recalls;
- fines, warning letters or untitled letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; and
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturers' communications on the subject of off-label use of their products.

In addition to the FDA's post-approval requirements, various state laws governing manufacturing, marketing, and distribution often apply, and state licenses may need to be obtained and renewed on a periodic basis in order to continue operations in specific states.

#### Biosimilars and Exclusivity

The ACA, signed into law in 2010, includes a subtitle called the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alteration or switch. Interchangeable biosimilars may be substituted for original BLA biologics at the pharmacy level, state pharmacy laws permitting.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. A reference biological product is granted twelve years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product, that does not result in a change in safety, purity, or potency. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical studies to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

A biologic can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. In some instances, the same studies can satisfy both PREA and pediatric exclusivity requirements.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the twelve-year reference product exclusivity period. Other aspects of the BPCIA, some of which may

impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to uncertainty.

# Government Regulation in Europe

In the EEA (which is composed of the 27 Member States of the European Union plus Norway, Iceland, and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. Under the Centralized Procedure, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure, the standard 210-day review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their
  respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure.
  Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be
  recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a
  National MA in any Member State at the time of application, it can be approved simultaneously in various Member
  States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and marketing exclusivity. In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical study data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial authorization of the reference product in the European Union. The 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric investigation plan. In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical study data can be waived by the

PDCO when the data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

Clinical studies. Clinical studies of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical studies of advanced therapy medicinal products. If the sponsor of the clinical study is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative. The sponsor must take out a clinical study insurance policy, and in most European Union countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical study.

Prior to commencing a clinical study, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the study protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the study will be conducted.

Under the new Regulation on Clinical Trials, which took effect in 2022, there is now in place a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the study protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical studies must be manufactured in accordance with cGMP.

The European Union requirements for research and investigation, approval, and post-market activities, may vary substantially from United States requirements. As such, approval in one jurisdiction is not predictive of potential for approval in the other jurisdiction.

# Product Approval Process Outside the United States and Europe

In addition to regulations in the United States and European Union, we will be subject to a variety of regulations in other jurisdictions governing manufacturing, clinical studies, commercial sales, and distribution of our future products. Whether or not we obtain FDA approval or MA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical studies or marketing in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval or MA approval. The requirements governing the conduct of clinical studies, product licensing, post-market activities and obligations, enforcement mechanisms, penalties for violation in the event of noncompliance, pricing, and reimbursement vary greatly from country to country.

#### United States Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market, and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

#### Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, the 340B Drug Discount program, TRICARE, and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by third-party payors. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

#### Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. The ACA, enacted in March 2010, has substantially changed healthcare financing and delivery by both governmental and private insurers. Among other things, the ACA included the following provisions:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs
  and biologic agents apportioned among these entities according to their market share in some government healthcare
  programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which through subsequent legislative amendments, were increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs to eligible

beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; and
- a licensure framework for follow-on biological products.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are undergoing or have undergone legal and constitutional challenges in the United States Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through the first 6 months of 2032 unless additional Congressional action is taken. These reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, and phased-in again on April 1, 2022 (between April 1, 2022 and June 30, 2022, a 1% cut took effect, with a 2% cut in place for the remainder of 2022). The Consolidated Appropriations Act of 2023 partially mitigated more severe Medicare pay cuts previously scheduled to begin on January 1, 2023; physician payment rates were reduced by 2% in 2023, and were reduced by 3.4% in 2024. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Notably, on August 16, 2022, President Biden signed the "Inflation Reduction Act of 2022" (IRA) into law, incorporating many key provisions of the "Build Back Better Act". Prescription drug price reform is a focal point of this landmark legislation that incorporates many proposals advanced over the last decade to overhaul drug costs under the Medicare program. Key provisions of the law permit CMS to negotiate Part D drug prices for an increasing number of drugs over a five-year period, replace the Medicare Coverage Gap Discount Program with a new Manufacturer Refund Program for drugs not subject to negotiation, and redesign the Part D benefit to eliminate the coverage gap and realign the cost responsibility in the initial and catastrophic phases of coverage among payors, manufacturers, Government and patients (capping out-of-pocket costs at US\$2,000 starting in 2025). In addition, the law penalizes drug manufacturers for price increases that outpace the rate of inflation (for products under Medicare Parts D/B).

The IRA follows years of attempts by the federal government to reform and/or control drug pricing. For example, at the federal level, the previous administration's budget proposal for fiscal year 2021 included a US\$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. The Biden administration has indicated that it will continue

to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical study and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical studies and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Another potential area of further healthcare reform is the 340B Drug Pricing Program, which was created by Congress in 1992 to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Drug manufacturers are incentivized to participate in this program as any manufacturer who wants their medication covered by Medicaid must also provide a discount to 340B covered entities, which includes a variety of healthcare entities that must abide by certain eligibility criteria in order to participate. This program requires drug manufacturers to provide outpatient drugs to eligible entities at a significantly discounted price which can result in savings between 20-50% or more.

Growth of the 340B program has continued to accelerate as more entities participate in the program and, thus, more patients qualify for 340B drugs. The value of the drug purchases by covered entities through the 340B program has grown exponentially year-over-year, with 2022 data indicating that discounted drugs purchased through the 340B program reached approximately \$53.7 billion annually. In the last decade drug manufacturers have opposed the 340B program publicly, as the program has experienced significant growth which corresponds to greater lost revenue potential for the manufacturers. There is a high degree of legal, legislative and public scrutiny as manufacturers have challenged some aggressive covered entity practices in litigation (with mixed success) and legislative reform proposals seek great transparency and accountability by the participating entities. Nonetheless, there is general industry consensus that the program will remain available in the long-term and there is a reasonable expectation that it will continue to have a material impact on the financial performance of manufacturers as program growth further erodes manufacturer revenue.

#### Data Privacy and Security Laws and Regulations

We are also subject to data privacy and security regulation by the federal government, states and non- United States jurisdictions in which we conduct our business. For example, HIPAA, as amended by HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit, or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state and non-United States laws govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities now and in the future could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion of products from reimbursement under government programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

For more on the risks associated with data privacy and security, please see "Risk Factors — Risks Related to Government Regulation — We are subject to stringent and often unsettled privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business."

#### **Employees**

As of December 31, 2024, we had five employees. Our employees are primarily located in Irvine, California. None of our employees are represented by a labor union or covered under a collective bargaining agreement, and we believe our relations with our employees are good.

#### **Facilities**

Our principal executive office is located at 5 Park Plaza, Suite 1750, Irvine, California 92614. In September 2021, we entered into a lease agreement for 8,000 square feet of office space located at this facility, with a lease term of 36 months beginning in December 2021 and ending in December 2024. In March 2024, we entered into an amendment to extend the lease to an additional five years. We may look for additional or alternate space for our operations, and we believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

# **Legal Proceedings**

On September 18, 2023, Odeon Capital Group LLC ("Odeon") filed a lawsuit against us in the Supreme Court of the State of New York, alleging that we failed to pay Odeon's deferred underwriting fee of \$1.25 million. Odeon claims that it served as the underwriter for Priveterra Acquisition Corp., the special purpose acquisition company with which Old AEON merged with and into in July 2023. Odeon seeks monetary damages for the full amount of its claimed underwriting fee, punitive damages, attorneys' fees and other amounts. In November 2023, we filed a motion to dismiss certain claims included in Odeon's complaint. In April 2024, we successfully obtained a dismissal of Odeon's non-breach of contract claims, including the tort claims, breach of covenant claim and associated punitive damages claim. Odeon's breach of contract claim is proceeding, with each party filing a summary judgment motion in March 2025, which the court is expected to decide upon in the coming months.

#### Item 1A. Risk Factors

#### RISK FACTORS

We are subject to various risks and uncertainties in the course of our business. You should carefully consider the risks and uncertainties described below and the other information in this report before making an investment in our Class A common stock, par value \$0.0001 per share ("Common Stock"). Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This report also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

# Risks Related to Our Business Operations and Financial Position

We have a limited operating history and have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.

We are a clinical stage biopharmaceutical company with a limited operating history. Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Old AEON was originally incorporated in 2012 but did not begin focusing its efforts and financial resources on the clinical development and regulatory approval of ABP-450 for therapeutic indications until 2019. The operating history upon which investors must evaluate our business and prospects is limited. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or a history of commercial operations. In addition, as an organization, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in the biopharmaceutical market. To date, we have not obtained any regulatory approvals for ABP-450 or generated any revenue from

product sales relating to ABP-450. On May 16, 2024, we announced the discontinuation of our Phase 2 double blind study of ABP-450 in the treatment of episodic migraine and chronic migraine, which had previously completed enrollment and dosing of patients, and ceased enrollment and dosing of patients in our open label extension study related to such study, in order to implement certain cash preservation measures while the Company continues to evaluate its strategic options. On July 9, 2024, we announced a strategic reprioritization to seek regulatory approval of ABP-450 as a biosimilar product in the United States through submission of a Biologics License Application, or BLA, under Section 351(k) of the Public Health Service Act, or a Section 351(k) BLA, using AbbVie Inc.'s product Botox as the reference product, for all of the indications for which Botox is approved, other than the cosmetic uses (for which we do not hold development or commercialization rights). We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on the next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies.

Because we have not yet received regulatory approvals, we are not permitted to market ABP-450 for any use in the United States or in any other territory, and as such, we have not generated any revenue from sales of ABP-450 to date. We have recorded income from operations of \$73.0 million for the year ended December 31, 2024, mainly due to gain on fair value of contingent consideration of \$100.8 million, and losses from operations of \$29.6 million and \$318.4 million for the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), respectively. We have recorded net income of \$42.0 million for the year ended December 31, 2024, mainly due to gain on fair value of contingent consideration, and net losses of \$60.7 million and \$324.0 million for the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), respectively. As of December 31, 2024, we had \$13 thousand in cash and cash equivalents. As a result of our ongoing losses, as of December 31, 2024 (Successor), we had an accumulated deficit of \$431.6 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to seek regulatory approval for, and begin to commercialize, ABP- 450, if approved. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses, or when, if at all, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, may adversely affect the market price of common stock and our ability to raise capital and continue operations.

Our management has concluded that uncertainties around our ability to raise additional capital raise substantial doubt about our ability to continue as a going concern. We will require additional financing to fund our future operations. Any failure to obtain additional capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our operations.

We have concluded that we do not have sufficient cash to fund our operations and to meet our obligations as they become due within one year from the date that our consolidated financial statements are issued and as a result, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is an issue raised as a result of ongoing operating losses and a lack of financing commitments to meet cash requirements, and is subject to our ability to generate a profit or obtain appropriate financing from outside sources, including obtaining additional funding from the sale of our securities or obtaining loans from third parties where possible. We will need to raise additional capital to fund our operations. We cannot assure you that we will be able to raise additional capital on commercially reasonable terms or at all. The perception that we may not be able to continue as a going concern may materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise and no assurance can be given that sufficient funding will be available when needed to allow us to continue as a going concern. This perception may also make it more difficult to operate our business due to concerns about our ability to meet our contractual obligations. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our stockholders may lose some or all of their investment in us.

We expect that we will continue to expend substantial resources for the foreseeable future in order to complete development of and seek regulatory approval for ABP-450 as a biosimilar to Botox, identify future potential therapeutic applications for ABP-450 and establish sales and marketing capabilities to commercialize ABP-450 across any approved indications.

As of the date of this Report, we expect to have sufficient cash to fund our operating plan into the fourth quarter of 2025. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much

faster than we currently expect or require more capital to fund our operations than we currently expect. Our future capital requirements depend on many factors, including:

- the timing of, and the costs involved in, obtaining regulatory approvals for ABP-450;
- the scope, progress, results and costs of researching and developing ABP-450, and conducting preclinical and clinical studies, including any studies required by the FDA to support submission of a Section 351(k) BLA;
- the cost of commercialization activities if ABP-450 is approved for sale, including marketing, sales and distribution costs;
- costs under our third-party manufacturing and supply arrangements for ABP-450 and any products we commercialize;
- the degree and rate of market acceptance of ABP-450, if approved, or any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses, and the terms and timing of any strategic collaboration or other arrangement;
- the terms of any conversion of the senior secured convertible notes in the principal amount of \$15.0 million (each a "Convertible Note" and together, the "Convertible Notes"), pursuant to a subscription agreement (the "Subscription Agreement"), dated as of March 19, 2024, with Daewoong Pharmaceutical Co. Ltd. ("Daewoong"), into shares of common stock, subject to certain conditions and limitations set forth in each Convertible Note
- costs of operating as a public company.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidate(s), technologies, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings or offerings of securities convertible into our equity, the ownership interest of stockholders will be diluted and the terms of any such securities may have a preference over our common stock. Debt financing, receivables financing and royalty financing may also be coupled with an equity component, such as warrants to purchase our capital stock, which could also result in dilution of our existing stockholders' ownership, and such dilution may be material.

Furthermore, if we raise additional capital through debt financing, we will have increased fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures to meet specified financial ratios, and other operational restrictions, any of which could restrict our ability to commercialize ABP-450 or to operate as a business and may result in liens being placed on our assets. If we were to default on any of our indebtedness, we could lose such assets. Additional funding may not be available on acceptable terms, or at all. The global credit and financial markets have experienced volatility and disruptions recently, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive.

Our future success currently depends entirely on the successful and timely regulatory approval and commercialization of our only product candidate, ABP-450. The development and commercialization of pharmaceutical products is subject to extensive regulation, and we may not obtain regulatory approvals for ABP-450 on a timely basis or at all.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of biological products, including ABP-450, are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. Regulatory approval of biologics in the United States requires the submission of a BLA to the FDA. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls demonstrating the safety, purity and potency of the biological product for its intended uses. FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize any product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidate, ABP-450, is safe and effective for its intended uses and in the case of biological products in the U.S., such as ABP-450, that such product candidate is safe, pure and potent for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates, including ABP-450, are promising, such data may not be sufficient to support approval for further development, manufacturing or commercialization of our product candidates by the FDA and other regulatory authorities. The FDA or other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program, requiring their alteration. The number and types of preclinical studies and clinical studies that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate.

The FDA and other regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including the following:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using products similar to our product candidates;
- the populations we evaluate in our the clinical trials may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate that a product candidate is safe, pure, potent, or effective for its intended uses, that such product candidate's clinical and other benefits outweigh its safety risks, or that such product candidate is biosimilar to a reference product;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a Section 351(k) BLA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- the FDA and other regulatory agencies may change their approval policies or adopt new regulations.

If ABP-450 fails to demonstrate the requisite safety, purity, potency or biosimilarity in our planned clinical studies or does not gain approval, our business and results of operations will be materially and adversely harmed.

We are currently planning to pursue approval for ABP-450 in the United States as a biosimilar to Botox, and our business presently depends entirely on our ability to obtain regulatory approval for ABP-450 and to successfully commercialize it in a timely manner. To date, as an organization, we have completed one clinical study evaluating ABP-450 for the treatment of cervical dystonia. We originally intended to pursue submission of an Original BLA seeking one or more potential therapeutic indications for ABP-450. However, our Phase 2 clinical trials for episodic and chronic migraine did not meet their respective primary endpoints. In May 2024, we announced the discontinuation of our Phase 2 clinical trials for episodic and chronic migraine in order to implement certain cash preservation measures. As a result, on July 9, 2024, we announced a strategic reprioritization to pursue a Section 351(k) BLA for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product, for which we would seek approval for all of the

indications for which Botox is approved, other than the cosmetic uses. We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies.

Although we believe ABP-450 represents a favorable candidate to develop as a biosimilar product, the FDA may indicate that a biosimilar pathway is not feasible, or prohibitively challenging, with a neurotoxin. For example, the FDA could require us to perform analytical testing procedures for ABP-450 that are not technologically feasible, or could disagree that the results from a single pivotal study could support submission of a Section 351(k) BLA. Even if the FDA acknowledges that ABP-450 has the potential to be developed as a biosimilar product, we may not be able to successfully complete our planned clinical study, or successfully prepare, submit, and obtain approval of a Section 351(k) BLA in a timely manner, or at all.

We have no products currently approved for sale and we may never be able to develop marketable products. We are not permitted to market ABP-450 in the United States unless we receive approval of a BLA from the FDA or approval of a similar application in any other countries permitted under the Daewoong Agreement. We can provide no assurances that ABP-450 will be successful in clinical studies or will ultimately receive regulatory approval. In addition, if we receive approval in one country, we may not receive a similar approval in any other jurisdiction.

Even if we obtain regulatory approvals for ABP-450 we may never be able to successfully commercialize ABP-450. We will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities, including by obtaining approval for coverage and adequate reimbursement from third-party and government payors, but we may not be successful in such a transition. Accordingly, we may not be able to generate sufficient revenue through the sale of ABP-450 to continue our business.

Clinical product development involves a lengthy, expensive and uncertain process. We may incur greater costs than we anticipate or encounter substantial delays or difficulties in our clinical studies.

We may not commercialize, market, promote or sell any product candidate, including ABP-450, without obtaining regulatory approval from the FDA or other regulatory agencies, and we may never receive such approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical studies have nonetheless failed to obtain regulatory approval of their product candidates.

The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired characteristics despite having progressed through preclinical studies and initial clinical trials. In particular, while we have conducted clinical studies evaluating ABP-450 in patients with cervical dystonia and migraines, we do not know whether our product candidates will perform similarly in future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. For example, our Phase 2 clinical trials for episodic and chronic migraine did not meet their respective primary endpoints. As a result, in May 2024, we announced the discontinuation of our Phase 2 clinical trials for episodic and chronic migraine in order to implement certain cash preservation measures.

We do not know whether our planned clinical trials will be completed on schedule, if at all. We may experience numerous unforeseen events prior to, during, or as a result of, clinical studies that could delay or prevent our ability to receive regulatory approval or to commercialize ABP-450 or any other product candidate, including the following:

- delays in reaching a consensus with regulatory authorities on the design or implementation of our clinical studies;
- regulators or institutional review boards, or IRBs, and ethics committees may not allow or authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- delays in identifying, recruiting and training suitable clinical investigators;

- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs. and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays or failures by our contract manufacturers, including Daewoong, to comply with current Good Manufacturing Practices, or cGMPs, or other applicable requirements, or to provide sufficient supply of ABP-450 for use in our clinical studies:
- the number of patients required for clinical studies of ABP-450 may be larger than we anticipate, enrollment in these clinical studies may be slower than we anticipate, participants may drop out of these clinical studies at a higher rate than we anticipate or fail to return for post-treatment follow-up or we may fail to recruit suitable patients to participate in a study;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice, or GCP, requirements or applicable regulatory rules and guidelines in other countries;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- clinical studies of ABP-450 may produce negative or inconclusive results;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical study operations, study
- sites or manufacturing facilities;
- we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs; or
- the impacts of any public health outbreaks (such as the COVID-19 pandemic) on our ongoing and planned clinical studies.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales or other sources. In addition, if we make manufacturing or formulation changes to ABP-450, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize ABP-450, if approved, or allow our competitors to bring competing products to market before we do, which could impair our ability to successfully commercialize ABP-450 and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical studies are inconclusive or if there are safety concerns or serious adverse events associated with ABP-450, we may:

- be delayed in obtaining regulatory approval, or not obtain regulatory approval at all;
- obtain approval in patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or be subject to the addition of labeling statements, such as warnings or contraindications;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical studies to support approval or be subject to additional post- marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a risk evaluation and mitigation strategy, or REMS;
- be sued; or
- experience damage to our reputation.

Our product development costs will also increase if we experience delays in testing or obtaining regulatory approvals. We do not know whether any of our preclinical studies or clinical studies will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA, a foreign regulatory authority, an ethics committee or an institutional review board may suspend our clinical studies at any time if it appears that we are failing to conduct a study in accordance with regulatory requirements, including among other things, the FDA's GCP regulations, that we are exposing participants to unacceptable health risks, or if the FDA other

regulatory agency finds deficiencies in our current or planned investigational new drug applications, or INDs, or other clinical study applications, or the conduct of these studies. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical studies, including our planned pivotal trial for ABP-450. If we experience delays in the commencement or completion of our clinical studies, or if we terminate a clinical study prior to completion, the commercial prospects of ABP-450 could be negatively impacted, and our ability to generate revenue from ABP-450 may be delayed.

Additionally, certain of our scientific advisors or consultants who receive compensation from us are likely to be investigators for our future clinical studies. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical study site and the utility of the clinical study itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of ABP-450. If we experience delays in the completion of, or termination of, any clinical study of ABP-450, the commercial prospects of ABP-450 will be harmed, and our ability to generate product revenue will be delayed. Moreover, any delays in completing our clinical studies will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition and prospects significantly.

Enrollment and retention of patients in clinical studies is an expensive and time-consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control. If we experience delays or difficulties in enrolling patients in clinical studies, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in our clinical studies is critical to our success. We may encounter difficulties in enrolling patients in our clinical studies and may compete against other clinical studies for the same pool of potential patients, thereby delaying or preventing development and potential regulatory approval of ABP-450. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our studies on a timely basis or at all.

Patient enrollment in clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol:
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- our ability to engage with patient communities and advocacy groups;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion.

We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for ABP-450 and any other product candidate and jeopardize our ability to obtain regulatory approval. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

## ABP-450 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit its commercial potential or result in significant negative consequences following any potential regulatory approval.

During the conduct of clinical studies, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused or contributed to these conditions and regulatory authorities may draw different conclusions from us and require additional testing to confirm these determinations, if they occur. Any adverse events or undesirable side effects caused by, or other unexpected properties of, ABP-450 could cause us, any future collaborators, IRB, or ethics committee or regulatory authorities to interrupt, delay or halt clinical studies of ABP-450 and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

In addition, it is possible that as we test ABP-450 in larger, longer and more extensive clinical studies, or as use of ABP-450 becomes more widespread if it receives regulatory approval, that illnesses, injuries, discomforts and other adverse events that were not observed in earlier studies conducted by us, or, in the case of ABP-450, by others using the same botulinum toxin, as well as conditions that did not occur or went undetected in previous studies, will be reported by subjects or patients. Many times, side effects are only detectable after investigational products are tested in large-scale pivotal studies or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that ABP-450 has side effects or causes serious or life-threatening side effects, the development of ABP-450 may fail or be delayed. Additionally, there is the risk that as botulinum toxins other than ABP-450 are approved for and studied in connection with a broader range of diseases and conditions and across a more diverse population, additional safety signals and other adverse events may be identified. All botulinum toxin products are required to include a class labeling that contains a boxed warning related to safety and we could be required to include additional warnings on our product labeling, if approved.

Additionally, if ABP-450 or any other product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop. Other potentially significant negative consequences associated with adverse events include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment:
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies:
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of ABP-450, if approved by the FDA or other regulatory authorities.

Results of other parties' clinical studies involving the same or a nearly identical botulinum toxin complex as ABP-450, or results in any preclinical studies we conduct, may not be predictive of future results of our clinical studies.

Success in clinical studies conducted by Daewoong and Evolus, Inc., or Evolus, involving a botulinum toxin that is identical or nearly identical to ABP-450 does not ensure that any clinical studies we conduct using ABP-450 will be successful and we will still need to submit our independently generated data to applicable regulatory agencies to support regulatory approval of ABP-450. Similarly, success in any preclinical studies or clinical studies that we conduct will not ensure that later clinical studies will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical

studies, even after positive results in earlier preclinical studies and earlier clinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks.

Additionally, our clinical studies may utilize an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate for either an existing approved drug or placebo. Most typically, open-label clinical studies test only the investigational product candidate and may do so at different dose levels. Open-label clinical studies are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical studies are aware when they are receiving treatment. Open-label clinical studies may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical studies may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical studies are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates when studied in a controlled environment with a placebo or active control.

Interim, topline or preliminary data from our clinical studies that we may announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose topline or preliminary data from our clinical studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive analysis of the data related to the particular study. Interim data for the studies we may complete are subject to the risk that one or more clinical outcomes may materially change as patient enrollment continues or more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Interim, topline and preliminary data also remains subject to audit and verification procedures that may result in the final data being materially different from the data previously published. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated, and any interim, topline or preliminary data should be viewed with caution until final data are available. Material adverse changes in the final data could result in significant harm to our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of our product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular pharmaceutical or biological product, pharmaceutical or biological product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product may be harmed, which could harm our business, operating results, prospects or financial condition.

We recently announced a strategic pivot to pursue regulatory approval for ABP-450 utilizing a 351(k) biosimilar pathway. Obtaining regulatory approvals under this novel approach may prove difficult, or even impossible, for a variety of reasons.

On July 9, 2024, we announced a strategic reprioritization to pursue submission of a Section 351(k) BLA for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product, for which we would seek approval for all of the indications for which Botox is approved, other than the cosmetic uses. We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies. To obtain regulatory approval for the commercial sale of ABP-450 as biosimilar product, we will be required to demonstrate to the satisfaction of the FDA, among other things, that ABP-450 is highly similar to a biological reference product already licensed by the FDA pursuant to an approved BLA, notwithstanding minor differences in clinically inactive

components, and that it has no clinically meaningful differences as compared to the reference product in terms of the safety, purity and potency of the product.

The potential to leverage the biosimilar pathway for a neurotoxin is untested, as no biosimilar has been approved utilizing Botox as the reference product. Among other things, Section 351(k) BLAs must include an assessment of toxicity and a clinical study or studies sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and for which licensure is sought for the proposed biological product. The amount of toxin in a single vial of Botox is miniscule and comparing toxicity vial-to-vial, which could be required by the FDA, may prove prohibitively difficult.

We plan to pursue the biosimilar pathway for ABP-450 because this pathway offers the potential to obtain FDA approvals for all FDA-approved indications for the reference product. If we are successful in demonstrating the biosimilarity of ABP-450 to Botox and obtain regulatory approval with respect to one indication, we believe the FDA could also approve ABP-450 for one or more indications currently listed on Botox's FDA-approved labeling without our having to conduct additional clinical trials for ABP-450, provided that the FDA determines that ABP-450 relies on a similar mechanism of action to Botox with respect to each such indication. However, even if we are able to demonstrate that ABP-450 is biosimilar to Botox with respect to one indication, the FDA may nevertheless determine that certain of Botox existing approved indications do not rely on a clearly established similar mechanism of action, which would limit our ability to seek approvals for ABP-450 without conducting additional trials. For example, pending FDA feedback, we plan to conduct a single pivotal clinical study in patients cervical dystonia. And the FDA could determine that a clinical study in cervical dystonia, a muscular disorder, even if successful, will not support a Section 350(k) BLA seeking approval for ABP-450 as a biosimilar in patients with migraine, a neurological disorder, or any of the other therapeutic (non-cosmetic) indications for which Botox is currently approved. Moreover, negative or ambiguous results from clinical trials of ABP-450 in certain patient populations, including the results from our Phase 2 trials, could adversely affect our ability to pursue certain indications in any Section 351(k) BLA. In addition, pursuant to our agreement with Daewoong, we do not have the rights to develop and commercialize ABP-450 for any of the cosmetic indications for which Botox has been approved, which further limits the market potential for ABP-450, even if we are successful in pursuing a biosimilar pathway.

Additionally, even if the FDA allows us to pursue a biosimilar pathway for ABP-450, and even if we are successful in demonstrating biosimilarity for ABP-450 to the satisfaction of the FDA, many manufacturers of reference biological products have used legislative, regulatory and other means, such as litigation, to delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

- settling, or refusing to settle, patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval;
- submitting citizen petitions to request the FDA to take administrative action with respect to prospective and submitted biosimilar applications;
- appealing denials of citizen petitions in United States federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payers, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from originator products to be trusted as safe and effective alternatives;
- implementing payer market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic standards;
- obtaining new patents covering existing products or processes, which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

In addition, any of these factors could prevent us from obtaining market acceptance for or otherwise successfully commercializing ABP-450, if approved as a biosimilar product.

Even if ABP-450 receives regulatory approval as a biosimilar or otherwise, it may fail to achieve the broad degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if ABP-450 receives regulatory approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The commercial success of ABP-450, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the convenience and ease of administration compared to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe a biosimilar product;
- the efficacy and potential advantages compared to alternative treatments and therapies;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the effectiveness of sales and marketing efforts;
- the strength of our relationships with patient communities;
- the timing of market introduction of our product candidate in relation to other potentially competitive products;
- the cost of treatment in relation to alternative treatments and therapies;
- the amount of upfront costs or training required for physicians to administer our product candidate;
- our ability to offer such product for sale at competitive prices;
- the strength of marketing and distribution support;
- the presence or perceived risk of potential product liability claims;
- the prevalence and severity of any side effects; and
- any restrictions on the use of the product together with other medications.

Our efforts to educate physicians, patients, third party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful.

If ABP-450 fails to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some therapeutic indications achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

Due to our limited resources and access to capital, we must prioritize the strategic pivot to pursue regulatory approval for ABP-450 utilizing a 351(k) biosimilar pathway and evaluate the development of certain therapeutic uses of ABP-450; these decisions may prove to be wrong and may adversely affect our business.

While we have shifted our focus to the development and potential commercialization of ABP-450 as a biosimilar to Botox, a key element of our future strategy is to identify additional conditions for which ABP-450 may warrant further development. However, there can be no assurances that we will be successful in identifying such conditions, such as gastroparesis and PTSD. Even if we are successful in identifying conditions that could potentially be treated with ABP-450, we may experience difficulties in identifying a proper treatment regimen, or we may fail to successfully develop ABP-450 or secure regulatory approval for such conditions.

Efforts to identify and pursue additional potential therapeutic uses of ABP-450 require substantial technical, financial and human resources, regardless of whether they are ultimately successful. Because we have limited financial and personnel resources, we may forgo or delay pursuit of opportunities with potential target indications that later prove to have greater commercial potential or a greater likelihood of success.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. We may focus our efforts and resources on potential therapeutic uses of ABP-450 that ultimately prove to be unsuccessful.

Even if we receive regulatory approval for ABP-450, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, limit or prohibit commercial distribution, prevent continued investigation and research and subject us to penalties if we fail to comply with applicable regulatory requirements. Additionally, ABP-450, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

For any regulatory approvals that we may receive for our ABP-450, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as ongoing compliance with cGMPs and GCPs for any clinical trials. In addition, manufacturers of biological products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs and other applicable regulations and standards. In addition, any regulatory approvals we may receive will require the submission of periodic reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product. Such approvals may also contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- the imposition of restrictions on the marketing or manufacturing of the product, suspension or withdrawal of product approvals or revocation of necessary licenses;
- the issuance of warning letters, untitled letters, or comparable notices describing alleged violations, which may be publicly available;
- mandated modifications to promotional materials or a requirement to provide corrective information to healthcare practitioners;
- required revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information;
- a requirement to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- the commencement of criminal investigations and prosecutions;
- the suspension of any ongoing clinical studies;
- a delay in approving or a refusal to approve pending applications or supplements to approved applications submitted by us;
- a refusal to permit products or active ingredients to be imported or exported to or from the United States or other applicable jurisdictions;
- a suspension of operations or the imposition of restrictions on operations, including costly new manufacturing requirements;
- a seizure or detention of products or a requirement that we initiate a product recall; and
- injunctions or the imposition of civil or criminal penalties.

Regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of ABP-450. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow to or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, given the similarity of ABP-450 to Jeuveau, any adverse developments with respect to Jeuveau, including adverse events or changes in regulatory status, may also directly impact the development, commercialization or regulation of ABP-450, if approved.

Even if we receive regulatory approval, coverage and adequate reimbursement may not be available for ABP-450, which could make it difficult for us to sell the product profitably.

Market acceptance and sales of ABP-450, if approved, will depend in part on the extent to which reimbursement for the product and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers.

Obtaining coverage and adequate reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor.

Third-party payors decide which therapies they will pay for and establish reimbursement levels. While no uniform policy for coverage and reimbursement exists in the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for ABP-450 will be made on a payor-by-payor basis. Therefore, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product or any related treatments. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs and biological products, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, because ABP-450 may be required to be physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may only be reimbursed for providing the treatment or procedure in which our product is used.

There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting pharmaceutical prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize ABP-450.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe a continued emphasis on cost containment initiatives in Europe, Canada and other countries could continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third party payors in the United States and other jurisdictions to cap or reduce health care costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on health care costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our products and may affect the prices we may set.

In the United States and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 has, among other things, led to aggregate reductions of Medicare payments to providers, which, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional action is taken by Congress. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. These laws and any laws enacted in the future may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D continue to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on the pharmaceutical industry cannot yet be fully determined but, is likely to be significant.

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for ABP-450, if approved, or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

# ABP-450, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

The pharmaceutical industry is highly competitive and requires an ongoing, extensive search for technological innovation. It also requires, among other things, the ability to effectively discover, develop, test and obtain regulatory approvals for novel products, as well as the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical professionals. Numerous companies are engaged in the development, manufacture and marketing of products competitive with those that we are developing.

Our primary competitors for ABP-450 in the injectable botulinum toxin pharmaceutical market for therapeutic use are:

- Botox, which is marketed by AbbVie, and since its original approval by the FDA in 1989 has been approved for multiple
  therapeutic indications, including migraine, cervical dystonia, upper and lower limb spasticity, strabismus, blepharospasm,
  overactive bladder, axillary hyperhidrosis, neurogenic detrusor overactivity and overactive bladder, and which is currently
  studying its botulinum toxin for therapeutic indications of episodic migraine, essential tremor and interstitial cystitis/bladder
  pain syndrome;
- Dysport, which is marketed by Ipsen Ltd. As an injectable botulinum toxin for the therapeutic indications of cervical dystonia and upper and lower limb spasticity, and which is currently studying its botulinum toxin for therapeutic indications of neurogenic detrusor overactivity and migraine (episodic and chronic);
- Xeomin, which is marketed by Merz Pharmaceuticals, LLC as an injectable botulinum toxin for the therapeutic indications of cervical dystonia, blepharospasm, chronic sialorrhea and upper limb spasticity; and
- Revance Therapeutics, Inc., or Revance, which is currently studying, preparing BLA submissions for and/or has received approval for, its injectable botulinum toxin, daxibotulinumtoxinA, for the therapeutic indications of cervical dystonia and

adult upper limb spasticity, and which has also entered into a collaboration and license agreement with Viatris Inc. to develop and commercialize a biosimilar to Botox.

We are also aware of competing botulinum toxins currently being developed or commercialized in the United States, European Union, Asia, South America and other markets. While some of these products may not meet United States regulatory standards, the companies operating in these markets may be able to produce products at a lower cost than United States and European manufacturers. In addition to the injectable botulinum toxin dose forms, we are aware that other companies are developing topical botulinum toxins for therapeutic indications. We will also face competition in our target therapeutic markets from other pharmaceutical products.

As more companies develop new intellectual property in our markets, the possibility of a competitor acquiring patent or other rights that may limit our products or potential products increases, which could lead to litigation. In addition to product development, testing, approval and promotion, other competitive factors in the pharmaceutical industry include industry consolidation, product quality and price, product technology, reputation, customer service and access to technical information.

# If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize ABP-450, if approved, or generate product revenue.

We do not have a sales or marketing infrastructure and have little experience in the sale, marketing, or distribution of pharmaceutical products. To successfully commercialize ABP-450, if approved, in the United States and other jurisdictions we may seek to enter, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market ABP-450 will be expensive and time-consuming and may divert significant management focus and resources, potentially delaying any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability, given that we have no experience as a company in commercializing products. We may seek to enter into collaborations with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into or maintain such agreements on favorable terms or at all. We can provide no assurance that any future collaborators will provide effective sales forces or marketing and distribution capabilities. We compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train and retain any of our own marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts of ABP-450. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

## We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2024, we had five employees. If ABP-450 receives regulatory approval, we would expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research, development, regulatory affairs, sales, marketing and distribution. In addition, we also expect to hire additional personnel in order to operate as a public company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. In addition, we must effectively integrate, develop and motivate a growing number of new employees, and maintain the beneficial aspects of our corporate culture. The expansion of our operations may lead to significant costs and may divert our management and business development resources. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our development and strategic objectives or disrupt our operations.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on third parties, including independent organizations, advisors and consultants, and CROs to provide certain services to support and perform our operations. There can be no assurance that the services of these third parties will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided, in particular the services provided by our CROs, is compromised for any reason, our clinical studies may be delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of ABP-450 or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other suitable outside contractors and consultants on economically reasonable terms, or at all.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates applicable regulations, including those laws requiring the reporting of true, complete and accurate information to regulatory agencies, manufacturing standards, and federal and state healthcare laws and regulations. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. We could face liability under the federal Anti-Kickback Statute and similar state laws. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, referrals, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical studies, which could result in significant regulatory sanctions and serious harm to our reputation. Further, should violations include promotion of unapproved (offlabel) uses of one or more of our products, we could face significant regulatory sanctions for unlawful promotion, as well as substantial penalties under the federal False Claims Act, or FCA, and similar state laws. Similar concerns could exist in jurisdictions outside of the United States as well. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

## Our potential international operations will expose us to risks, and failure to manage these risks may adversely affect our operating results and financial condition.

We expect to have operations both inside and outside the United States if ABP-450 is approved for commercial sale in multiple jurisdictions. International operations are subject to a number of inherent risks, and our future results could be adversely affected by a number of factors if we seek and obtain the necessary approvals, including:

- requirements or preferences for domestic products, which could reduce demand for our products;
- differing existing or future regulatory and certification requirements;
- management communication and integration problems resulting from cultural and geographic dispersion;
- greater difficulty in collecting accounts receivable and longer collection periods;
- difficulties in enforcing contracts;
- difficulties and costs of staffing and managing non-United States operations;
- the uncertainty of protection for intellectual property rights in some countries;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products;
- more stringent data protection standards in some countries;
- regulatory concerns limiting ability to import or export products;
- greater risk of a failure of foreign employees to comply with both United States and foreign laws, including export and antitrust regulations, the United States Foreign Corrupt Practices Act, or the FCPA, quality assurance and other healthcare regulatory requirements and any trade regulations ensuring fair trade practices;
- heightened risk of unfair or corrupt business practices in certain geographies and of improper or fraudulent sales arrangements that may impact financial results and result in restatements of, or irregularities in, financial statements;
- foreign currency exchange rates;
- potentially adverse tax consequences, including multiple and possibly overlapping tax structures and difficulties relating to repatriation of cash; and

political and economic instability, political unrest and terrorism. These and other factors associated with international
operations could harm our ability to gain future revenue and, consequently, materially impact our business, results of
operations and financial condition.

# If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of ABP-450.

We face an inherent risk of product liability as a result of the clinical testing of ABP-450 and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for ABP-450;
- termination of clinical study sites or entire study programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical study participants or cancellation of clinical studies;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to study participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any products we develop; and
- a decline in our share price.
- Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of ABP-450. We currently carry product liability insurance covering our clinical studies.

Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing ABP-450, we intend to expand our insurance coverage to include the sale of ABP-450; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

# If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop ABP-450, conduct our clinical studies and commercialize ABP-450.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management. We believe that our future success is highly dependent upon the contributions of our senior management, particularly Marc Forth, our Chief Executive Officer, as well as other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical studies or the commercialization of ABP-450 or any future products we develop.

In addition, we could experience difficulties attracting and retaining qualified employees in the future. For example, competition for qualified personnel in the pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information or that their former employers own their research output.

Our business involves the use of hazardous materials, and we and our third-party manufacturer and supplier must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our R&D and manufacturing activities in the future may, and Daewoong's manufacturing and supplying activities presently do, involve the controlled storage, use and disposal of hazardous materials, including botulinum toxin type-A, a key component of ABP-450, and other hazardous compounds. We and Daewoong are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at Daewoong's facilities pending their use and disposal. We and Daewoong cannot eliminate the risk of contamination, which could cause an interruption of Daewoong's manufacturing processes, our commercialization efforts or our business operations and could cause environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by Daewoong for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent.

### Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by one or more 5% shareholders over a rolling three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes, such as research tax credits, to offset its post- change taxable income or income tax liabilities, as applicable, may be limited. As of December 31, 2024 and 2023, the Company had federal net operating loss ("NOL") carryforwards of \$112.1 million and \$87.3 million, respectively, which will begin to expire in 2036. The Company had state NOLs of \$140.5 million and \$116.2 million as of December 31, 2024 and 2023, respectively, which will begin to expire in 2034. As of December 31, 2024 and 2023, the Company has federal research and development ("R&D") credit carryforwards of \$6.9 million and \$6.1 million, respectively, which will begin to expire in 2039. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. Similar rules may apply under state tax laws. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

#### Changes in tax laws may impact our future financial position and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us or our suppliers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

Prior to the Business Combination, Priveterra identified material weaknesses in its internal control over financial reporting. In 2024, AEON identified additional material weaknesses in its internal control over financial reporting. One or more of these material weaknesses could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner, which may adversely affect investor confidence in us and materially and adversely affect our business and operating results.

Prior to consummation of the Business Combination, Priveterra management identified a material weakness in its internal control over financial reporting, related to Priveterra's accounting for complex financial instruments. In 2024, AEON management identified additional material weaknesses in its internal control over financial reporting related to its fiscal year 2023, related to the Business Combination and for the valuation of complex financial instruments, and the lack of segregation of duties pertaining to the financial reporting process due to lack of sufficient resources. To respond to the material weaknesses, we have devoted and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. We plan to enhance our processes by designing and implementing controls to review the results of valuations and estimates, including the completeness and accuracy of relevant data elements included in the valuation or estimate. We also plan to engage additional qualified

resources and/or hire additional staff to ensure these incremental controls are properly implemented and to ensure proper segregation of duties around the financial reporting process. Management continues to be actively engaged to take steps to remediate the material weaknesses, including enhanced processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand the nuances of the complex accounting standards that apply to our consolidated financial statements, providing enhanced access to accounting literature, research materials and documents, and increased communication among our personnel and third-party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

#### Risks Related to our Reliance on Third Parties

We rely on the Daewoong Agreement to provide us exclusive rights to commercialize and distribute ABP-450 in certain territories. Any termination or loss of significant rights, including exclusivity, under the Daewoong Agreement would materially and adversely affect our development or commercialization of ABP-450.

Pursuant to the Daewoong Agreement, we have secured an exclusive license from Daewoong, a South Korean pharmaceutical manufacturer, to import, distribute, promote, market, develop, offer for sale and otherwise commercialize and exploit ABP-450 for therapeutic indications in certain territories including the United States, the European Union, the United Kingdom, Canada, Australia, Russia, Commonwealth of Independent States and South Africa. The Daewoong Agreement imposes on us obligations relating to exclusivity, territorial rights, development, regulatory approval, commercialization, payment, diligence, sublicensing, intellectual property protection and other matters. For example, we are obligated to use commercially reasonable efforts to obtain regulatory approval of ABP-450 and obtain from Daewoong all of our product supply requirements for ABP-450. In addition, under the Daewoong Agreement, we are required to submit our commercialization plan to a Joint Steering Committee, or JSC, comprised of an equal number of development and commercial representatives from Daewoong and us, for review and input.

Although the Daewoong Agreement provides us with final decision-making power regarding the marketing, promotion, sale and/or distribution of ABP-450, any disagreement among the JSC would be referred to Daewoong's and our respective senior management for resolution if the JSC is unable to reach a decision within thirty days, which may result in a delay in our ability to implement our commercialization plan or harm our working relationship with Daewoong. Further, under the Daewoong Agreement, we may not purchase, sell or distribute any injectable botulinum toxin that is launched in the covered territories after the effective date of the Daewoong Agreement other than ABP-450 in a covered territory or sell ABP-450 outside a covered territory.

The initial term of the Daewoong Agreement will expire on the later of December 20, 2029 or the fifth anniversary of our receipt of approval from the relevant governmental authority necessary to market and sell ABP-450 in any of the aforementioned territories. The Daewoong Agreement will renew for unlimited additional three-year terms after the expiration of the initial term. We or Daewoong may terminate the Daewoong Agreement if the other party breaches any of its duties or obligations and such breach continues without cure for ninety days, or thirty days in the case of a payment default, or, if such breach is not capable of being cured, immediately by delivery of written notice. The Daewoong Agreement will terminate without notice upon our bankruptcy or insolvency or if we assign our business or the Daewoong Agreement in whole or in part for the benefit of creditors. On March 19, 2024, we entered into a Fourth Amendment to the Daewoong Agreement (the "Daewoong Agreement Amendment") with Daewoong, which amends the Daewoong Agreement to provide that Daewoong may terminate the Daewoong Agreement if, over any six- month period, (a) we cease to commercialize ABP-450 in each of the territories specified in the License Agreement and (b) we cease to advance any clinical studies of ABP-450 in any such territories. The Daewoong Agreement Amendment also provides that, in the event that the License Agreement is terminated for the foregoing reasons, Daewoong will have the right to purchase all Know-How (as defined in the License Agreement) related to ABP-450 for a price of \$1.00 (the "Termination Purchase Right"). The Termination Purchase Right will terminate and expire upon Daewoong's sale of 50% of its common stock, including common stock held by its affiliates and common stock that would be issued upon an Automatic Conversion or Optional Conversion of the Convertible Notes (as defined in the Convertible Notes).

We will be the sole owner of any marketing authorization we pursue related to therapeutic indications of ABP-450 in a covered territory. This will include ownership of any BLA that we may submit to the FDA, MAA that we may submit to the EMA, NDS that we may submit to Health Canada, and any other approvals that we may receive in a covered territory. However, if we do not renew the Daewoong Agreement following any initial or renewal term, or if Daewoong terminates the Daewoong Agreement due to a breach by us, we are obligated to transfer our rights in such marketing authorizations to Daewoong.

If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Daewoong and Daewoong may have the right to terminate our license. Any termination or loss of rights under the Daewoong Agreement would materially and adversely affect our ability to develop and commercialize ABP-450, which in turn would have a material adverse effect on our business, operating results and prospects. If we were to lose our rights under the Daewoong Agreement, we believe it would be difficult or impossible for us to find an alternative supplier of a botulinum toxin type-A complex. In addition, to the extent the alternative supplier has not secured regulatory approvals in a jurisdiction, we would have to expend significant resources, including performing additional clinical studies, to obtain regulatory approvals that may never be obtained or require several years to obtain, which could significantly delay commercialization. We may be unable to raise additional capital to fund our operations during this extended time on terms acceptable to us or at all. If we were to commercialize ABP-450 and later experience delays as a result of a dispute with Daewoong, the demand for ABP-450 could be materially and adversely affected.

We currently rely solely on Daewoong to manufacture ABP-450, and as such, any production or other problems with Daewoong could adversely affect us. The manufacture of biologics is complex and Daewoong may encounter difficulties in production that may impact our ability to provide supply of ABP-450 for clinical studies, our ability to obtain regulatory approval, or our ability to obtain commercial supply of our products, which, if approved, could be delayed or stopped.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We depend solely upon Daewoong to manufacture ABP-450. Any failure or refusal by Daewoong to supply ABP-450 could delay, prevent or impair our clinical development or commercialization efforts. The Daewoong Agreement also provides for a fixed price related to the supply of ABP-450 for ten years or for five years after the receipt of regulatory approvals, and if a change in price were to occur, it could impair our ability to obtain necessary quantities of ABP-450. Although alternative sources of supply may exist, the number of third-party suppliers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New suppliers of any product candidate would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product candidate. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non- infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs which may be passed on to us. We will also need to verify, such as through a manufacturing comparability study, that any new contract manufacturing organization or manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. We may be unsuccessful in demonstrating the comparability of clinical suppliers which could require conducting additional clinical studies.

In addition, there are risks associated with large scale manufacturing for clinical studies or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for ABP-450, there is no assurance that Daewoong will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If Daewoong is unable to produce sufficient quantities for clinical studies, including preclinical studies, or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our reliance on Daewoong entails additional risks, including reliance on Daewoong for regulatory compliance and quality assurance, the possible breach of the Daewoong Agreement by Daewoong, and the possible termination or nonrenewal of the Daewoong Agreement at a time that is costly or inconvenient for us. Our failure, or the failure of Daewoong, to comply with applicable regulations, such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation, could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of the product candidate or drugs, import alerts or detentions preventing import of product into the United States or other territories, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of ABP-450. Our dependence on Daewoong also subjects us to all of the risks related to Daewoong's business, which are all generally beyond our control. Daewoong's ability to perform its obligations under the Daewoong Agreement is dependent on its operational and financial health, which could be negatively impacted by several factors, including changes in the economic, political and legislative conditions in South Korea and the broader region in general and the ability of Daewoong to continue to successfully attract customers and compete in its market. Daewoong's lack of familiarity with,

or inability to effectively operate, the facility and produce products of consistent quality, may harm our ability to compete in our market.

In addition, we are ultimately responsible for distribution of products under any authorization or approval we hold to investigate or market ABP-450. We do not own a manufacturing facility and we have never supervised manufacturing operations, but we have regulatory obligations to review batch records and release of the investigational product for our clinical studies. Further, we will have similar regulatory obligations if the product is marketed and could be held responsible for any distribution of adulterated or misbranded ABP-450, even if caused by Daewoong's noncompliance. If Daewoong's facility were to be damaged, destroyed or otherwise unable to operate or comply with regulatory requirements, whether due to earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, political unrest, power outages or otherwise, or if operations at the facility were disrupted for any other reason, such an event could negatively affect our ongoing preclinical studies and clinical studies and, if ABP-450 is approved, jeopardize Daewoong's ability to manufacture ABP-450 as promptly as we or our customers expect or possibly at all. If an event occurred that prevented Daewoong from using all or a significant portion of its manufacturing facility due to damaged critical infrastructure, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for Daewoong to supply enough ABP- 450 to continue our business for a substantial period of time.

# A material breach by us of the terms of our license and settlement agreement with Medytox, Inc. could have a material adverse effect on our business.

In May 2021, Medytox, Inc., or Medytox, brought a case against Old AEON in the United States District Court for the Central District of California, or the Medytox Litigation, alleging, among other things, that Daewoong stole Medytox's botulinum toxin bacterial strain, or the BTX strain, and misappropriated certain trade secrets of Medytox, including the process used to manufacture ABP-450 using the BTX strain, and that our and Daewoong's activities conducted in the United States gave rise to liability for misappropriation of trade secrets. Medytox sought, among other things, (i) actual, consequential and punitive damages, (ii) a reasonable royalty, as appropriate, (iii) disgorgement of any proceeds or profits, (iv) injunctive relief prohibiting us from using Medytox's trade secrets to manufacture, offer to sell, or sell therapeutic BTX products, including ABP-450, and (v) attorneys' fees and costs.

The Medytox Litigation was another step in an ongoing dispute involving Medytox and Allergan, on the one side, and Evolus, Daewoong and us on the other side. In June 2017, Medytox brought a civil lawsuit of a similar nature against Evolus, Daewoong and Old AEON in the Superior Court of the State of California, which we refer to as the Superior Court Litigation, and a separate lawsuit in October 2017 against Daewoong in South Korea, which we refer to as the Korea Litigation. The lawsuit filed in the Superior Court of the State of California alleged claims substantially similar to the Medytox Litigation and was subsequently stayed on grounds of forum non conveniens, because the underlying facts that gave rise to the complaint occurred in South Korea, among other reasons. We are not a party to the Korea Litigation. In April 2018, the Superior Court of the State of California dismissed Medytox's suit against Daewoong without prejudice on the basis that Medytox had brought a substantially similar proceeding against Daewoong in South Korea, and continued a stay of the case as to us and Evolus. In February 2021, the Superior Court of the State of California dismissed Medytox's suit against Old AEON without prejudice, following Medytox's filing of a notice of settlement of the case based on a settlement it entered with Evolus.

Additionally, in January 2019, Allergan and Medytox filed a complaint against Daewoong and Evolus with the United States International Trade Commission, or the United States ITC, alleging that the BTX strain used in Evolus' Jeuveau product is manufactured based on misappropriated trade secrets of Medytox and therefore its importation is an unfair act. The Administrative Law Judge issued a final determination in December 2020. The final determination concluded that a violation of Section 337 of the Tariff Act of 1930 had occurred, and the United States ITC issued a limited exclusion order forbidding entry of Jeuveau into the United States for 21 months and a cease and desist order prohibiting Daewoong and Evolus from engaging in the importations, sale for importation, marketing, distribution, offering for sale, the sale after the importation of, or other transfers of Jeuveau within the United States for 21 months. The 21-month ban was stayed as a result of a settlement agreement between Evolus and Medytox in February 2021.

Effective June 21, 2021, Old AEON entered into a settlement and license agreement with Medytox, or the Medytox Settlement Agreement, pursuant to which, among other things, Medytox agreed (a) to dismiss all claims against us in the Medytox Litigation, (b) to pursue dismissal of the appeals related to the December 2020 final determination of the United States ITC and agreed that as a result of such dismissal the final determination would be vacated, (c) to file appropriate documents in the Korea Litigation and related actions in support of the terms of the settlement, and (d) not to revive or otherwise pursue the Superior Court Litigation with respect to

us. In addition, Medytox granted us a non-exclusive, royalty bearing license to Medytox's botulinum toxin strain and specific trade secrets alleged to have been misappropriated in the litigation to commercialize and manufacture specific botulinum neurotoxin products including ABP-450 worldwide, with the exception of South Korea. In exchange for the license, we issued Medytox 26,680,511 shares of Old AEON common stock, par value \$0.0001 per share, and agreed to pay Medytox single-digit royalties on the net sales of licensed products for 15 years following our first \$1.0 million in commercial sales of neurotoxin products.

Medytox can terminate the Medytox Settlement Agreement if we materially breach any material provision of the agreement, either immediately upon written notice if the breach is incurable or after 60 days if capable of remedy. Additionally, Medytox may terminate the Medytox Settlement Agreement with 15 days of written notice if we or our affiliates or sublicensees challenge the validity, enforceability, scope, or protected status of Medytox's botulinum strain and specific trade secrets alleged to have been misappropriated in the litigation. If the Medytox Settlement Agreement were terminated, Medytox would be able to revive the Medytox Litigation and other claims against us, and may seek an injunction or other ruling against us in the Korea Litigation, any one of which could result in us losing access to ABP-450 and the manufacturing process and require us to negotiate a new license with Medytox for continued access to ABP-450. We may not be able to successfully negotiate such license on terms acceptable to us or at all. If we are unable to license ABP-450, we may not be able to find a replacement product candidate on a timeline favorable to us, if at all, without expending significant resources and being required to seek additional regulatory approvals, which would be uncertain, time consuming and costly.

We rely, and will continue to rely, on third parties, CROs and consultants to conduct all of our preclinical studies and clinical studies. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for ABP-450.

We do not currently have the ability to independently conduct any preclinical studies or clinical studies. We rely, and will continue to rely, on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to conduct preclinical studies and clinical studies on ABP-450. The third parties with whom we currently or may in the future contract for execution of any of our preclinical studies and clinical studies play a significant role in the conduct of these studies and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to any of our current or future programs. Although we rely on these third parties to conduct our preclinical studies and clinical studies, we remain responsible for ensuring that each of our preclinical studies and clinical studies is conducted in accordance with the investigational plan and protocol. Moreover, the FDA and other similar regulatory authorities require us to observe both good laboratory practices, or GLP, and animal welfare requirements for preclinical studies, and to comply with GCPs for conducting, monitoring, recording and reporting the results of clinical studies to ensure that the data and results are scientifically credible and accurate, and that the study subjects are adequately informed of the potential risks of participating in clinical studies. Our reliance on CROs and other third parties does not relieve us of these regulatory and legal responsibilities. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP, GCP or other requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, the execution of preclinical studies and clinical studies, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. If the third parties or consultants conducting our clinical studies do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to GLPs, or our clinical study protocols or GCPs, or for any other reason, we may need to conduct additional clinical studies or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our preclinical studies and clinical studies may be extended, delayed or terminated or may need to be repeated. Further, any noncompliance that results in data integrity issues could put any regulatory approval we receive at risk of withdrawal, and could subject us to regulatory sanctions due to failure to adequately oversee the third parties we rely upon. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for and will not be able to, or may be delayed in our efforts to, successfully commercialize ABP-450.

## Public health outbreaks, epidemics or pandemics (such as the COVID-19 pandemic) may materially and adversely affect our business and operations.

The COVID-19 pandemic previously adversely affected, and the COVID-19 pandemic or other actual or threatened public health outbreaks, epidemics or pandemics may in the future adversely affect, among other things, our research and development efforts, clinical trial operations, manufacturing and supply chain operations, administrative personnel, third-party service providers, and business partners.

While the COVID-19 pandemic did not materially adversely affect our business operations during the twelve months ended December 31, 2024, economic and health conditions in the United States and across most of the globe continue to change rapidly and may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, a continuing widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 or a future public health outbreak could materially affect our business and the value of our common stock. The ultimate impact of the COVID-19 pandemic or a similar public health outbreak is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material adverse effect on our business, results of operations and financial condition.

# We may use third-party collaborators to help us develop, validate or commercialize any new products, and our ability to commercialize such products could be impaired or delayed if these collaborations are unsuccessful.

We may license or selectively pursue strategic collaborations for the development, validation and commercialization of ABP-450. In any third-party collaboration, we would be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation, and we would have limited control over the amount and timing of resources and effort that our collaborators would dedicate to the development or commercialization of our product candidates. Our collaborators may not cooperate with us or perform their obligations under our agreements with them at all or as expected. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our current and future product candidates may be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Our collaborators could also independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates, fail to properly maintain or defend our intellectual property rights or infringe the intellectual property rights of third parties, exposing us to litigation. Disputes with our collaborators could also impair our reputation or result in development and commercialization delays, decreased revenues and could cause litigation expenses.

In addition, we may face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical studies, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for ABP-450 or our future product candidates, the costs and complexities of manufacturing and delivering ABP-450 or our future product candidates to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of ABP-450 or our future product candidates, reduce or delay development programs, delay potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop and commercialize ABP-450 or our future product candidates or bring them to market and generate revenue.

#### **Risks Related to Intellectual Property**

If we or any of our current or future licensors, including Daewoong, are unable to maintain, obtain or protect intellectual property rights related to ABP-450 and any future product candidates we may develop, or if the scope of any protection obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends, in part, on our ability to seek, obtain and maintain intellectual property protection in the United States and other countries with respect to our technologies. We and Daewoong currently rely upon a combination of trademarks, trade secret protection, confidentiality agreements and proprietary know- how. Additionally, Daewoong has obtained a United States patent related to its proprietary botulinum toxin manufacturing process. We also intend to protect our proprietary technology and methods by, among other things, filing for and obtaining United States and foreign patent applications related to our proprietary technology, inventions, methods of use, and improvements that are important to the development and implementation of our business. However, due to existing patent eligibility laws, we do not expect to obtain patent protection for the composition of matter for botulinum toxin, as it is produced by Clostridium botulinum, a gram-positive, rod-shaped, anaerobic, spore-forming, motile bacterium with the ability to produce the botulinum toxin. Although we only own one issued patent covering our migraine injection paradigm (U.S. Patent No. 11,826,405), we do not own any other issued patents, but we have filed certain provisional and non-provisional patent applications with the United States Patent and Trademark Office, or USPTO, related to other novel and proprietary methods of utilizing ABP-450 for therapeutic purposes. These patent applications may fail to result in any issued patents with claims that cover ABP-450, in the United States or in other foreign countries, and the patents, if issued, may be declared invalid or unenforceable.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. In addition, it is possible that we will fail to identify patentable aspects of our R&D output before it is too late to obtain patent protection. Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our R&D output, such as our employees and third-party consultants, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with ABP-450 and any future product candidates.

Other parties have developed technologies that may be related to or competitive to our own technologies and such parties may have filed or may file patent applications, or may have obtained or may obtain patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or any future issued patents. We may not be aware of all third-party intellectual property rights potentially relating to ABP-450 and any future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and in other jurisdictions are typically not published until 18 months after filing, or, in some cases, not at all. Therefore, we cannot know with certainty whether the inventors of our pending patent applications were the first to make the inventions claimed in those patent applications, or that they were the first to file for patent protection of such inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our patent applications may not issue and any patents, if issued, may be challenged and invalidated or rendered unenforceable.

Even in the event our non-provisional patent applications are granted, or if we in-license issued patent rights from third parties, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and any such patents may be challenged in courts or patent offices in the United States and abroad and later declared invalid or unenforceable. For example, we may be subject to a third-party submission of prior art to the USPTO challenging the validity of one or more claims of any such patents. A third party may also claim that any such patents are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put any such patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, we may become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings and other similar proceedings in foreign jurisdictions (e.g., opposition proceedings) challenging the validity, priority or other features of patentability of any such patent rights. Challenges to our patent rights may result in loss of patent rights, exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the scope and duration of the patent protection of ABP-450 or future product candidates. Such challenges also may result in substantial cost and require significant time from our

scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of botulinum toxins, patents protecting such product candidates might expire before or shortly after they are commercialized. As a result, our patent applications, even if issued, may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to ABP-450 or future product candidates, including biosimilar versions of such products.

Even if they are unchallenged, our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. If the patent protection provided by our patent applications, if issued, is not sufficiently broad to impede such competition, our ability to successfully commercialize ABP-450 and future product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Under the Daewoong Agreement, we license the trademark for Nabota associated with ABP-450 from Daewoong; however, we may ultimately pursue alternative trademarks and branding for ABP-450. Our or Daewoong's trade secrets and other confidential proprietary information and those of our future licensors could be disclosed or competitors could otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we or any of our current or future licensors may encounter significant problems in protecting and defending our or their intellectual property both in the United States and internationally. If we or any of our current or future licensors are unable to prevent material disclosure of the non-patented intellectual property related to ABP-450 to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business.

In addition to the protection afforded by patents, trademarks, confidentiality agreements and proprietary know-how, we may in the future rely upon in-licensed or acquired patents or proprietary technology for the development of ABP-450. We may not be able to in-license third party patents necessary to commercialize ABP-450 on commercially reasonable terms, or at all, which could materially harm our business. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property or maintain the existing intellectual property rights we have licensed, we may be required to expend significant time and resources to redesign ABP-450 or future product candidates, or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis, and we may have to abandon development of ABP-450 or future product candidates which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, the strength of any patents that issue from our non-provisional patent applications or that we may in-license from third parties in the technology and healthcare fields involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights in such fields can be uncertain. Our pending patent applications and any patent applications that we may in-license may fail to result in issued patents with claims that cover ABP-450, in the United States or in other foreign countries, and the issued patents that we may in-license may be declared invalid or unenforceable.

We are reliant on the ability of Daewoong, as the licensor of our only product candidate, to maintain its intellectual property and protect its intellectual property against misappropriation, infringement or other violation. We may not have primary control over Daewoong's or our future licensors' patent prosecution activities. Furthermore, we may not be allowed to comment on prosecution

strategies, and patent applications currently being prosecuted may be abandoned by the patent owner without our knowledge or consent.

With respect to patents that are issued to our licensors, or patents that may issue on patent applications, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. As a licensee, we are reliant on Daewoong and our future licensors to defend any third-party claims. Our licensors may not defend or prosecute such actions as vigorously or in the manner that we would have if entitled to do so, and we may be impacted by any judgment or settlement resulting from such actions. Also, a third party may challenge the validity of our in-licensing transactions. Furthermore, even if they are unchallenged, any of our future in-licensed patents and patent applications may not adequately protect the licensors or our intellectual property or prevent others from designing around their or our claims.

Third-party claims of intellectual property infringement, misappropriation or violation, or challenges related to the invalidity or unenforceability of any issued patents we may obtain or in-license may prevent or delay our development and commercialization efforts or otherwise adversely affect our results of operations.

Our commercial success depends in part on our and any of our future collaborators avoiding infringement, misappropriation or other violation of the intellectual property and related proprietary rights of third parties. Competitors and other entities that possess intellectual property rights related to the use of botulinum toxins in the fields of neurology and gastroenterology have developed large portfolios of patents and patent applications in fields relating to our business. In particular, there are patents held by third parties that relate to the treatment with botulinum toxin-based products. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the technology, medical device and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter partes reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we plan to develop ABP-450. As the technology, medical device and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidate may be subject to claims of infringement of the patent rights of third parties, regardless of their merit.

There may be third-party patents or patent applications with claims to materials, methods of manufacture or methods for treatment related to the use or manufacture of ABP-450. Because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that ABP-450 or any future product candidates may infringe. It is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to ABP-450 and future product candidates because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology or incorrectly conclude their invalidity or unenforceability. In addition, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover ABP-450 or future product candidates and third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Even if we believe claims brought against us are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed. In order to successfully challenge the validity of any such United States patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent or find that ABP-450 or future product candidates did not infringe any such claims. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of ABP-450, the holders of any such patents may be able to block our ability to commercialize ABP-450 unless we obtain a license under the applicable patents or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our methods of use, the holders of any such patent may be able to block our ability to develop and commercialize ABP-450 unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

In addition to claims of patent infringement, third parties may bring claims against us asserting misappropriation or other violations of proprietary technology or other information in the development, manufacture and commercialization of ABP-450. Defense of such a claim would require dedicated time and resources, which time and resources could otherwise be used by us toward the maintenance of our own intellectual property and the development and commercialization of ABP-450 or for operational upkeep and manufacturing of our product. In addition, there could be public announcements of the results of hearings, motions or other

interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. We have been, and may in the future become, party to, or be threatened with, adversarial proceedings or litigation where our competitors or other third parties may assert claims against us, alleging that our therapeutics, manufacturing methods, formulations, administration methods or delivery devices infringe, misappropriate or otherwise violate their intellectual property rights, including patents and trade secrets. For example, in the past, Medytox asserted that we and Daewoong were employing their proprietary technology without authorization, and other third parties may make similar assertions about us or any of our current or future licensors, including Daewoong, in the future. For more information regarding our litigation with Medytox, please see "Risk Factors — Risks Related to Our Reliance on Third Parties — A material breach by us of the terms of our license and settlement agreement with Medytox, Inc. could have a material adverse effect on our business."

Likewise, any patents that may issue from our pending patent applications or any future in-licensed patents and pending patent applications may also be subject to priority, validity, inventorship and enforceability disputes in court or before administrative bodies in the United States or abroad. If we or any of our licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of ABP-450 or future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Parties making claims against us or any of our current or future licensors may request and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize ABP-450. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business which time and resources could otherwise be used by us toward the maintenance of our own intellectual property and the development and commercialization of ABP-450 or for operational upkeep and manufacturing of our product. In the event of a successful claim of infringement, misappropriation or other violation of a third party's intellectual property, we or any of our current or future licensors may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties which may not be commercially available, or pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical study supplies or allow commercialization of ABP-450. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize ABP-450, which could harm our business significantly. Similarly, third-party patents could exist that might be enforced against our products, resulting in either an injunction prohibiting our sales, or with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

## We may become involved in lawsuits to protect or enforce our intellectual property or the patents and other intellectual property of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including any future patents we may acquire, or any future patents or other intellectual property licensed to us by our licensors, including Daewoong. As a result, we or any of our current or future licensors may be required to file infringement claims to stop third-party infringement or unauthorized use. Even if resolved in our favor, this can be unpredictable, expensive, particularly for a company of our size, and time-consuming and may cause us to incur significant expenses and distract our scientific and management personnel from their normal responsibilities. In addition, in an infringement proceeding, a court may decide that a patent of ours or any of our current or future licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of such patents at risk of being invalidated or interpreted narrowly. Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to any of our future patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us or any of our current or future licensors may fail or may be invoked against us or our licensors by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management or the management of any of our current or future licensors, including Daewoong. We may not be able, alone or with any of our current or future licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If securities analysts or investors perceive these results to be negative, the market price for our common stock could be significantly harmed. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or other intellectual property proceedings longer than we could. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with the initiation and continuation of litigation or other intellectual property proceedings could compromise our ability to raise the funds necessary to continue our clinical studies, continue our internal research programs, or in-license needed technology, or otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize ABP-450 and future product candidates are subject, in part, to the terms and conditions of licenses granted to us by others, including Daewoong. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are heavily reliant upon our license from Daewoong to certain proprietary technology that is important or necessary to the development of ABP-450 and future product candidates. Additionally, further development and commercialization of ABP-450 and future product candidates may require us to enter into additional license or collaboration agreements. For more information regarding our reliance on Daewoong and future collaboration agreements, please see "Risk Factors — Reliance on Third Parties."

Our current and any future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize ABP-450 and future product candidates. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products, including in territories covered by our licenses.

In some circumstances, we may not have the right to control the maintenance, prosecution, preparation, filing, enforcement, defense or litigation of patents and patent applications that we license from or license to third parties and are reliant on our licensors or licensees to do so. We thus cannot be certain that activities such as patent maintenance and prosecution by our licensors have been or will be conducted consistent with our best interests or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. If our licensors fail to maintain such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize future product candidates that are the subject of such licensed rights and our right to exclude third parties from commercializing competing products could be adversely affected. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. Disputes may arise with respect to our current or future licensing agreements, including disputes relating to:

- the scope of rights granted under the license agreements and other interpretation-related issues;
- our financial or other obligations under the license agreements;
- the extent to which ABP-450 and future product candidates infringe on intellectual property of the licensors that is not subject to the licensing agreements;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreements and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

• the priority of invention of patented technology.

For example, the Daewoong Agreement does not contain provisions regarding the ownership of any intellectual property that results from inventions or improvements related to ABP-450. There could be disputes in the future related to the inventorship or ownership of inventions and know-how resulting from our improvements to ABP-450 and future related product candidates, although we believe we are the sole owner of our intellectual property and have developed it independently of Daewoong.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize ABP-450 and future product candidates. If our licenses are terminated, we may lose our rights to develop and market ABP-450 and future product candidates, lose patent protection for ABP-450 and future product candidates, experience significant delays in the development and commercialization of ABP-450 and future product candidates, or incur liability for damages. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with ABP-450 and future product candidates.

Furthermore, if the Daewoong Agreement or any future licenses are terminated, or if the underlying patents or other intellectual property rights fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or competitive to ours and we may be required to cease our development and commercialization of ABP-450 and future product candidates. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize ABP-450 and future product candidates. In addition, certain of these license agreements may not be assignable by us without the consent of the respective licensor, which may have an adverse effect on our ability to engage in certain transactions. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

## We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents relating to ABP-450 and any future product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States; a patent owner may have limited remedies, and in some cases foreign authorities may even force us to grant a compulsory license to competitors or other third parties. As such, we or our licensors may not be able to obtain patent protection for ABP-450 and future product candidates outside the United States. Consequently, we may not be able to prevent third parties from using our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement any of our patents that may issue from our pending patent applications, or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us.

We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

#### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidates, including ABP-450, we and our licensors also rely on trade secrets protection to protect our and their unpatented know-how, technology and other proprietary information, in order to maintain our and their competitive positions.

We and our licensors seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, consultants, advisors and other third parties. We have entered into invention assignment agreements with our current employees. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we or our licensors have taken to protect our respective proprietary technologies will be effective.

Additionally, we cannot guarantee that we or our licensors have entered into such agreements with each party that may have or has had access to our respective trade secrets. We also seek to preserve the integrity and confidentiality of our data and trade secrets by taking security measures with respect to our information technology systems; however, our or our licensors' systems and security measures may be breached, and we may not have adequate remedies for any breach. As a result, we or our licensors could lose our trade secrets and third parties could use our or our licensors' trade secrets to compete with ABP-450 or future product candidates.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Competitors or third parties could purchase ABP-450 and future product candidates and attempt to replicate or reverse engineer some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside the scope of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

# We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or asserting ownership of what we regard as our own intellectual property.

We employ individuals who were previously employed at other pharmaceutical companies including certain of our anticipated competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information, including intellectual property and other proprietary information, of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. We may not be successful in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Any litigation or the threat thereof may adversely affect our ability to hire or retain employees. A loss of key personnel or their work product could diminish or prevent our ability to commercialize ABP-450, which could have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may also be subject to claims that former employers or other third parties have an ownership interest in our patents or other intellectual property. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus

an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. We or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of any patent protection covering ABP-450 and future product candidates. Disputes about the ownership of intellectual property may have a material adverse effect on our business, financial condition, results of operations and prospects.

# If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Although we have filed applications to register trademarks in the United States and other jurisdictions, we currently do not own any registered trademarks and our current and future trademark applications in the United States and in foreign jurisdictions may not be allowed or may subsequently be opposed, as has been done in the United States with the Company's trademark applications for AEON and related marks. Further, our unregistered or future registered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Third parties may assert that we are using trademarks or trade names that are confusingly similar to their marks. If any third-party were able to establish that our trademarks or trade names were infringing their marks, that third-party may be able to block our ability to use the infringing trademark or trade name. In addition, if a third-party were to bring such a claim, we would be required to dedicate time and resources to fight the claim, which time and resources could otherwise be used toward the maintenance of our own intellectual property.

Parties making claims against us may request and obtain injunctive or other equitable relief, which could prevent our ability to use the subject trademarks or trade names. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee and management resources from our business, and their time and resources could otherwise be used toward the maintenance of our own intellectual property and may otherwise be expensive and time- consuming, particularly for a company of our size. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement. We may be required to re-brand one or more of our products or services offered under the infringing trademark or trade name, which may require substantial time and monetary expenditure. Third parties could claim senior rights in marks which might be enforced against our use of trademarks or trade names, resulting in an injunction prohibiting our sales under those trademarks or trade names.

Our efforts to enforce or protect our proprietary rights related to trademarks may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

### Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make ABP-450 and future product candidates that are similar to ours, but that are not covered by the claims of the patents that we may license or own in the future;
- we, or our license partners or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;

- others may circumvent our regulatory exclusivities, such as by pursuing approval of a competitive product candidate via the traditional approval pathway based on their own clinical data, rather than relying on the abbreviated pathway provided for biosimilar applicants;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to now or in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a nonexclusive basis;
- our competitors might conduct R&D activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or other intellectual property rights of others may have an adverse effect on our business; or
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

### **Risks Related to Government Regulation**

#### Our business and products are subject to extensive government regulation.

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the United States and other countries, principally by the FDA and other similar regulatory authorities. Daewoong is also subject to extensive regulation by the FDA and the South Korean regulatory authorities as well as other regulatory authorities. Our failure to comply with all applicable regulatory requirements, or Daewoong's or any future collaborator's failure to comply with applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws may subject us to operating restrictions and criminal prosecution, monetary penalties and other enforcement or administrative actions, including sanctions, warning letters, import alerts, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs.

In the event ABP-450 receives regulatory approval, we and our direct and indirect suppliers, including Daewoong, will remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in requirements that we implement REMS programs, requirements that we complete government mandated clinical studies, and government enforcement actions, including those relating to labeling, advertising, marketing and promotion, as well as regulations governing manufacturing controls.

If we experience delays in obtaining approval or if we fail to obtain approval of ABP-450, the commercial prospects for ABP-450 may be harmed and our ability to generate revenue will be materially impaired.

In addition, in the course of our activities we may collect information from clinical study subjects or other individuals that subjects us to a variety of rapidly evolving laws regarding privacy, data protection and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personal data. Data breaches or other violations of these laws could subject our business to significant penalties and reputational harm. For more information on data security and privacy, see "Risk Factors — Risks Related to Government Regulation — We are subject to stringent and often unsettled privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business."

Even if we obtain FDA approval for ABP-450 in the United States, we may never obtain approval for or commercialize such candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may

not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

The misuse or off-label use of our approved products, if any, may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about pharmaceutical products. These regulations include standards and restrictions for direct-to- consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. In particular, a product may not be promoted for uses or indications that are not specifically approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. For example, if we receive regulatory approval for ABP-450 and if we are found to have promoted uses that are not part of ABP-450's approved labeling, we may be subject to enforcement action from the FDA and other regulatory agencies, as applicable, and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed in order to resolve FDA enforcement actions. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions or other restrictions on the sale or marketing of our products and other operations or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry. In addition, off-label promotion could expose us to liability under the FCA, as well as similar state laws.

Physicians may also misuse ABP-450, if approved, or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If ABP-450 is misused or used with improper techniques or is determined to cause or contribute to patient harm, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, result in sizable damage awards against us that may not be covered by insurance and subject us to negative publicity resulting in reduced sales of our products. Furthermore, the use of ABP-450, if approved, for indications other than those cleared by the FDA, may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. Any of these events could harm our business and results of operations and cause the price of our common stock to decline.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

We are subject to applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the FCA, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e.g., healthcare providers, physicians and third party payors), are subject to

extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. We also may be subject to patient information and privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

The Anti-Kickback Statute, which prohibits the knowing and willful offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including but not limited to cash, improper discounts, and free or reduced price items and services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. A claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of anti-kickback and other applicable laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. Some state law equivalents of the above federal laws, such as the Anti-Kickback Statute and FCA, apply to items or services regardless of whether the good or service was reimbursed by a government program, so called all- payor laws. These all-payor laws could apply to our sales and marketing activities even if the Anti-Kickback Statute and FCA laws are inapplicable.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information also implicate our business. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition to other federal laws, state laws and foreign laws, such as the General Data Protection Regulation in the European Union, or the GDPR, create the potential for substantial penalties in the event of any non-compliance with the applicable data privacy and data protection laws.

The federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to

report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulatory guidance. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA or an all-payor law, then we could be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment, reputational harm and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs.

State and federal authorities have aggressively targeted pharmaceutical companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements with pharmacies and other healthcare providers that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines, have been ordered to implement extensive corrective action plans, and have in many cases become subject to consent decrees severely restricting the manner in which they conduct their business, among other consequences. Additionally, federal and state regulators have brought criminal actions against individual employees responsible for alleged violations. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the FCPA and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-United States officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund R&D activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the

United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections at domestic and foreign manufacturing facilities from March 2020 until July 2021. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus may lead to other inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns hinder or prevent the FDA or other regulatory authorities from conducting regular inspections or review, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are subject to stringent and often unsettled privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information or personal data, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous United States federal and state laws and regulations relating to privacy and security of personal information. Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect. For example, the State of California enacted the California Consumer Privacy Act of 2018, or CCPA, which went into effect on January 1, 2020 and requires companies that process information on California residents to make new disclosures to consumers about their data collection, use and sharing practices, allow consumers to opt out of certain data sharing with third parties and provide a new cause of action for data breaches. Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency that is vested with authority to implement and enforce the CCPA and the CPRA. New legislation proposed or enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts.

In addition, all 50 states and the District of Columbia have enacted breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential information experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify patients or other counterparties of a security breach.

Although we may have contractual protections with our service providers, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our service providers may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

In addition, the GDPR became applicable on May 25, 2018 in respect of processing operations carried out in the context of the activities of an establishment in the European Economic Area, or EEA, and any processing relating to the offering of goods or services to individuals in the EEA and/or the monitoring of their behavior in the EEA.

While we do not at this time collect, store, use or process data on behalf of existing customers or for anyone residing in the United Kingdom or Europe, if we do so in the future, we will be subject to the rigorous and time-intensive policies of the GDPR. There is no assurance that our own limited privacy and security- related safeguards will protect us from all risks associated with data privacy and information security.

### Risks Related to Being a Public Company and Ownership of Our Securities

### The price of our common stock may be volatile.

The price of our common stock has been and is likely to continue to be volatile. The market price for our common stock may be influenced by many factors, including the other risks described in this section of the Report entitled "Risk Factors" and the following:

- our ability to advance our current or potential future product candidates throughout applicable clinical studies;
- results of preclinical studies for our current or potential future product candidates, or those of our competitors;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our future products;
- the success of competitive products or technologies;
- introductions and announcements of new product candidates by us or our competitors, and the timing of these introductions or announcements:
- actions taken by regulatory authorities with respect to our future product candidates, clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including, but not limited to, those with any sources of manufacturing supply and future commercialization collaborators;
- market conditions in the pharmaceutical and biotechnology sectors;
- market conditions and sentiment involving companies that have recently completed a business combination with a special purpose acquisition company ("SPAC");
- announcements by us or our competitors of significant acquisitions, strategic alliances, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for its products;
- ability or inability to raise additional capital and the terms on which it is raised;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or the industry generally;
- failure or the failure of our competitors to meet analysts' projections or guidance that our or our competitors may give to the market:
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock, including as a result of the significant number of shares of our common stock (i) that the Sellers retained pursuant to the FPA Termination Agreements and may resell in the future, and (ii) that Daewoong may be issued upon any conversion of the Convertible Notes and may resell in the future;
- sales of our common stock by us or by our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, public health crises and other calamities; and
- general economic, industry and market conditions.

In addition, the stock markets in general, and the markets for SPAC post-business combination businesses, pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility. This volatility can often be unrelated to the operating performance of the underlying business. These broad market and industry factors may seriously harm the market price of our common stock, regardless of AEON's operating performance.

Sales of a substantial number of our securities in the public market by our existing securityholders could cause the price of our common stock and Private Placement Warrants to fall.

Sales of a substantial number of our shares of common stock or Private Placement Warrants in the public market by the Registered Holders or by our other existing security holders, or the perception that those sales might occur, could depress the market price of our common stock and Private Placement Warrants and could impair our ability to raise capital through the sale of additional equity securities. As of March 2025, holders of our Private Placement Warrants are entitled to exercise such warrants, on a cashless basis, in exchange for shares of our common stock, calculated based on the 10-day volume average weighted price prior to the Company's receipt of the warrant holders' notice. Such warrant holders may seek to monetize the return on their investment in the warrants quickly, which could adversely impact the price of our stock. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock and Private Placement Warrants. The sale of all the securities, particularly at high volumes over a short period of time could result in a significant decline in the public trading price of our securities. Despite such a decline in the public trading price, some of the Registered Holders may still experience a positive rate of return on the securities they purchased due to the differences in the purchase prices described elsewhere in this Report. Other security holders may not be able to experience positive rates of return on securities they purchase.

The resale, or expected or potential resale, of a substantial number of our shares of common stock in the public market could adversely affect the market price for our shares of common stock and make it more difficult for you to sell your shares of common stock at times and prices that you feel are appropriate. In particular, as a result of the termination of the Forward Purchase Agreements, the Sellers are entitled to keep their shares and, following effectiveness of a registration statement related thereto, may resell a significant number of shares of common stock in the market with respect to the shares that they retained pursuant to the FPA Termination Agreements. In addition, a significant number of shares of common stock may be issued upon conversion of the Convertible Notes pursuant to certain automatic or optional conversions provisions under the Convertible Notes, and such shares of common stock may be resold by Daewoong in the future following effectiveness of a registration statement related thereto. Furthermore, we expect that, because there will be a large number of shares registered, the applicable selling securityholders will continue to offer such covered securities for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to a registration statement may continue for an extended period of time. In addition, because the current market price of our common stock is higher than the price certain selling securityholders paid for their securities, there is more likelihood that selling securityholders holding shares of common stock will sell their shares as soon as the applicable registration statement is declared effective and any applicable lock-up restrictions expire.

Certain existing stockholders of AEON acquired securities at a price below the current trading price of such securities, and may experience a positive rate of return based on the current trading price or at lower trading prices. Future investors in AEON may not experience a similar rate of return.

Prior to consummation of the Business Combination, certain existing stockholders of AEON acquired shares of common stock or Private Placement Warrants at prices below, and in some cases considerably below, the current trading price of our common stock or for no cash consideration at all. It is possible that these stockholders may experience a positive rate of return based on the current trading price or at lower trading prices.

Given the relatively lower purchase prices that some of our stockholders paid to acquire some of their securities compared to the current trading price of our shares of common stock, these stockholders, some of whom are registered holders pursuant to registration statements we are obligated to file to register the resale of shares of common stock, in some instances may earn a positive rate of return on their investment, which may be a significant positive rate of return, depending on the market price of our shares of common stock at the time that such stockholders choose to sell their shares of common stock. For example, based on the closing price of our Common Stock of \$0.73 on March 17, 2025, the Sponsor and its permitted transferees could experience, with respect to 47,921 Founder Shares (which excludes 47,921 Founder Shares subject to the restrictions and forfeiture provisions set forth in the Sponsor Support Agreement), potential profit of up to \$0.44 per share of Common Stock (although such shares are subject to a one-year lockup from the date of Closing), or \$3.2 million in the aggregate, based on the Sponsor's initial purchase price of Founder Shares prior to Priveterra's initial public offering at a price of approximately \$0.288 per share. Investors who purchased units in Priveterra's initial public offering or who purchased our Common Stock on NYSE American following consummation of the Business Combination may not experience a similar rate of return on the securities they purchased due to differences in the purchase prices and the prevailing trading price. See the section of this Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information on the potential profits the other registered holders may experience.

## Fluctuations in our stock price may yield material changes in the valuation of the underlying derivatives securities associated with our capital structure, including our Contingent Consideration Shares.

We currently have multiple financial instruments, including underlying derivatives which we account for in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815 Derivatives and Hedging: Embedded Derivatives. In accordance with the guidance, we value these derivatives at each reporting period and recognize the corresponding adjustments to fair value as changes to other income (expense), net in our Statements of Operations. The fair values are estimated using certain pricing models, which involve various inputs, including our current stock price as of the end of each reporting period. Period-over-period fluctuations in our stock price may result in material changes in the fair value of these derivatives, which in turn may materially impact (positively and negatively) our Statements of Operations.

# We will require additional capital, which additional financing may result in restrictions on our operations or substantial dilution to our stockholders, to support the growth of our business, and this capital might not be available on acceptable terms, if at all.

To date, our primary sources of capital have been placements of stock, sales of shares of Evolus, and debt financing agreements. We cannot be certain when or if our operations will generate sufficient cash to fully fund our ongoing operations or the growth of our business. We intend to continue to make investments to support our business, which may require us to engage in equity or debt financings to secure additional funds. Additional financing may not be available on terms favorable to us, if at all. If adequate funds are not available on acceptable terms, we may be unable to invest in future growth opportunities, which could harm our business, operating results, and financial condition. If we incur additional debt, the debt holders would have rights senior to holders of common stock to make claims on our assets, and the terms of any debt could restrict our operations. If we undertake discretionary financing by issuing equity securities, our stockholders may experience substantial dilution.

We may sell common stock, convertible securities or other equity securities in one or more transactions at a price per share that is less than the price per share paid by current stockholders. If we sell common stock, convertible securities, or other equity securities in more than one transaction, stockholders may be further diluted by subsequent sales. Additionally, future equity financings may result in new investors receiving rights superior to our existing stockholders. Because our decision to issue securities in the future will depend on numerous considerations, including factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future issuances of debt or equity securities. As a result, our stockholders bear the risk of future issuances of debt or equity securities reducing the value of our common stock and diluting their interests.

## We may incur significant costs from class action litigation due to the expected stock volatility.

The price of common stock may fluctuate for many reasons, including as a result of public announcements regarding the progress of development efforts for our main product candidate, ABP-450, the development efforts of competitors, the addition or departure of key personnel, variations in quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years, including since the Closing. In addition, recently there has been significant stock price volatility involving the shares of companies that have recently completed a business combination with a SPAC. When the market price of a stock has been volatile as our common stock's price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. Additionally, there has recently been a general increase in litigation against companies that have recently completed a business combination with a SPAC alleging fraud and other claims based on inaccurate or misleading disclosures. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. Any such lawsuit could also divert the time and attention of management.

### Any failure to meet the continued listing requirements of NYSE American could result in a delisting of our common stock.

On February 3, 2025, the Company received a written notice of non-compliance from the NYSE American LLC ("NYSE American") stating that the Company is not in compliance with continued listing standards of Section 1003(a)(i) of the NYSE American Company Guide (the "Company Guide"). The Company has been provided with a compliance period of 18 months to regain compliance. To regain compliance, the Company must submit a plan by March 5, 2025, advising of actions taken or will be taken to regain compliance with the continued listings standards of the Company Guide by August 3, 2026 (the "Plan"). The Plan will be subject to approval and periodic reviews by the NYSE American to monitor compliance with the Plan. If the Company does not submit a plan or if the Plan is not accepted, or if the Plan is accepted but the Company is not in compliance with the Minimum

Requirement by August 3, 2026, or if the Company does not make progress consistent with the Plan, then the NYSE American will initiate delisting proceedings as appropriate.

If we fail to satisfy the continued listing requirements of NYSE American, such as failing to satisfy any applicable corporate governance requirements or the minimum closing bid price requirement, NYSE American may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of our securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the NYSE American minimum bid price requirement or prevent future non-compliance with NYSE American's listing requirements. Additionally, if our securities are not listed on, or become delisted from, NYSE American for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if our securities were quoted or listed on NYSE American or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

We are an "emerging growth company" and it cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors, which may make it more difficult to compare our performance with other public companies.

We are an emerging growth company as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies for up to five years following the completion of the Merger, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. To the extent we continue to take advantage of any of these exemptions, the information that we provide stockholders may be different than what is available with respect to other public companies. Investors may find the our common stock less attractive because we will continue to rely on these exemptions. If some investors find the our common stock less attractive as a result, there may be a less active trading market for the common stock, and the stock price may be more volatile.

An emerging growth company may elect to delay the adoption of new or revised accounting standards. Because we have made this election, Section 102(b)(2) of the JOBS Act allows us to delay adoption of new or revised accounting standards until those standards apply to non-public business entities. As a result, the financial statements contained in this Report and those that we will file in the future may not be comparable to companies that comply with public business entities revised accounting standards effective dates.

We are also a "smaller reporting company" as such term is defined in the Rule 12b-2 of the Exchange Act, meaning that the market value of our common stock held by non-affiliates plus any proposed aggregate amount of gross proceeds to us as a result of any offering is less than \$700 million and our annual revenue is less than \$100 million during the most recently completed fiscal year. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements, including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements. Investors could find our common stock less attractive because it may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the trading price may be more volatile.

Future sales and issuances of our common stock or rights to purchase our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our common stock price to fall.

We expect to have sufficient cash to fund our operating plan into the fourth quarter of 2025. However, we have based these estimates on numerous assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Significant additional capital will be needed in the future to continue our planned operations, including further development of our product candidate ABP-450, preparing INDs or equivalent filings, conducting preclinical studies and clinical trials, commercialization efforts, expanded R&D activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner as determined from time to time. If we sell common stock, convertible securities or other equity securities, existing investors may be materially diluted by subsequent sales. New investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to the 2023 Incentive Award Plan, or "the 2023 Plan", our board of directors (the "Board") or our compensation committee (the "Compensation Committee") is authorized to grant equity-based awards to our employees, directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2023 Plan is 53,332 shares. Additionally, the number of shares of our common stock reserved for issuance under the 2023 Plan will automatically increase on January 1 of each year, beginning in 2024 and ending in 2033, by an amount equal to the lesser of 4% of the number of fully-diluted number of shares outstanding (as calculated pursuant to the terms of the 2023 Plan) on the final day of the immediately preceding calendar year or (ii) such lesser number of shares as is determined by our Board.

Pursuant to the Employee Stock Purchase Program, or ESPP, our employees will have the opportunity to purchase shares of our common stock at a discount through accumulated payroll deductions. Initially, the aggregate number of shares of common stock that may be issued under the ESPP is 6,780 shares. In addition, the number of shares of common stock available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2024 and ending in 2033 by an amount equal to the lesser of (a) 1% of the fully-diluted number of shares outstanding (as calculated pursuant to the terms of the ESPP) on the final day of the immediately preceding calendar year or (b) such lesser number of shares as is determined by our Board. Unless our Board elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause the price of our common stock to fall.

Our issuance of additional shares of common stock or other equity securities of equal or senior rank would, all else being equal, have the following effects:

- existing stockholders' proportionate ownership interests would decrease;
- the amount of cash available per share of common stock, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding share of common stock would be diminished; and
- the market price of shares of our common stock may decline.

The Warrants may never be in the money, and they may expire worthless and the terms of such Warrants may be amended in a manner adverse to a holder if holders of at least a majority of the then-outstanding Warrants approve of such amendment.

The Warrants were issued in registered form pursuant to the Warrant Agreement. The Warrant Agreement provides that the terms of the Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision. Any amendment to the terms of the Private Placement Warrants requires the consent of the Company and the holders of a majority of the Private Placement Warrants.

On March 29, 2024, we issued a notice of redemption to holders of the Public Warrants announcing that we would redeem all Public Warrants, for a redemption price of \$7.20 per Public Warrant, that remained outstanding as of 5:00 p.m. New York City time on April 29, 2024 (the "Redemption Date"). Immediately after the Redemption Date, no Public Warrants remained outstanding. We may receive up to an aggregate of approximately \$45.9 million from the cash exercise of the Private Placement Warrants. The exercise price of each of our Private Placement Warrants is \$828.00 per warrant and the reported sales price of our Common Stock on March 17, 2025 was \$0.73. The likelihood that holders of Private Placement Warrants will exercise their Private Placement Warrants, and therefore any amount of cash proceeds that we may receive, is dependent upon the trading price of our Common Stock. If the trading price for our Common Stock does not maintain a price above \$828.00 per share, we do not expect holders to exercise their Private Placement Warrants for cash. The Private Placement Warrants may be exercised on a cashless basis at any time and we would not

receive any proceeds from such exercise, even if the Private Placement Warrants are in-the-money. We expect to use the net proceeds from the exercise of such securities, if any, for general corporate purposes, which may include acquisitions or other strategic investments. We will have broad discretion over the use of any proceeds from the exercise of such securities. Any proceeds from the exercise of such securities would increase our liquidity, but we are not currently budgeting for any cash proceeds from the exercise of the Private Placement Warrants when planning for our operational funding needs.

## Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls and procedures can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

The obligations associated with being a public company involve significant expenses and require significant resources and management attention, which may divert from AEON's business operations.

As a public company, AEON is subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company's business and financial condition. The Sarbanes-Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. The listing requirements of NYSE American also require that we satisfy certain corporate governance requirements. As a result, AEON will incur significant legal, accounting and other expenses that AEON did not previously incur. AEON's entire management team and many of its other employees will need to devote substantial time to compliance, and may not effectively or efficiently manage its transition into a public company.

These rules and regulations will result in AEON incurring substantial legal, financial and accounting compliance costs in addition to other expenses and will make some activities more time-consuming and costly. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations will likely make it more difficult and more expensive for AEON to obtain director and officer liability insurance, and it may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. As a result, it may be difficult for AEON to attract and retain qualified people to serve on its Board, its Board committees or as executive officers.

Provisions in AEON's certificate of incorporation, AEON's bylaws and Delaware law have anti-takeover effects that discourage an acquisition of AEON by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management, which could depress the trading price of our common stock.

AEON's certificate of incorporation, bylaws, and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. AEON's certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our Board without stockholder approval and may contain voting, liquidation, dividend and other rights superior to common stock;
- create a classified Board whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our Board, the chairperson of the Board or our chief executive officer or president;
- prohibit stockholder action by written consent;

- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our Board to adopt, amend or repeal our bylaws; and
- require supermajority votes of the holders of common stock to amend specified provisions of our certificate of incorporation and bylaws. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

AEON's certificate of incorporation and bylaws designate the Court of Chancery of the State of Delaware as the exclusive forum for certain state law litigation that may be initiated by our stockholders and the United States federal district courts as the exclusive forum for certain securities law actions, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum and increase the costs for our stockholders to pursue certain claims against us.

Pursuant to AEON's bylaws and certificate of incorporation, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, AEON's certificate of incorporation and bylaws (including their interpretation, validity or enforceability); or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Stockholders cannot waive compliance with the Securities Act, the Exchange Act or any other federal securities laws or the rules and regulations thereunder.

Unless we consent in writing to the selection of an alternate forum, the United States federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these exclusive forum provisions. The forum selection provisions in our bylaws may limit our stockholders' ability to litigate disputes with us in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, these forum selection provisions may impose additional litigation costs for stockholders who determine to pursue any such lawsuits against us.

#### General Risks

Our business and operations would suffer in the event of computer system failures, including but not limited to our information technology systems, infrastructure and data, or those of our third-party vendors, contractors or consultants failing, becoming unavailable, or suffering security breaches, losses or leakages of data and other disruptions, which could result in disruption of our services, compromise sensitive information (including personal information) related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third

parties, and as a result we manage a number of third-party vendors and other contractors and consultants who have access to our confidential information.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to breakdown or other damage from service interruptions, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions, including ransomware attacks, over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusions, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our current or future product development programs. For example, the loss of clinical study data from completed or any future ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidate could be delayed.

We cannot assure you that our data protection efforts and our investment in information technology will prevent breakdowns, data leakages, breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption or delay of the development of ABP-450 and future product candidates. Furthermore, significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information, which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to actual or perceived unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on third parties to provide services and technology necessary for the operation of our business. Any failure of one or more of our vendors, suppliers or licensors to provide these services or technology could have a material adverse effect on our business.

We rely on third-party vendors to provide critical services, including, among other things, services related to accounting, billing, human resources, and information technology that we cannot or do not provide ourselves. We depend on these vendors to ensure that our corporate infrastructure will consistently meet our business requirements. The ability of these third-party vendors to successfully provide reliable and high quality services is subject to technical and operational uncertainties that are beyond our control.

While we may be entitled to damages if our vendors fail to perform under their agreements with us, the amount of damages we receive may be limited. In addition, we do not know whether we will be able to collect on any award of damages or that these damages would be sufficient to cover the actual costs we would incur as a result of any vendor's failure to perform under its agreement with us. Any failure of our corporate infrastructure could have a material adverse effect on our business, financial condition and results of operations. Upon expiration or termination of any of our agreements with third-party vendors, we may not be able to replace the services provided to us in a timely manner or on terms and conditions, including service levels and cost, that are favorable to us and a transition from one vendor to another vendor could subject us to operational delays and inefficiencies until the transition is complete.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We currently only have limited research coverage and may never obtain extensive research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we obtain equity research analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. Analysts will establish and publish their own periodic financial projections for the business of AEON. These projections may vary widely and may not accurately predict the results AEON actually achieves. AEON's stock price may decline if its actual results do not match the projections of these securities research analysts. The price of our common stock could also decline if one or more equity research analysts downgrades our common stock or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

Operating as a public company requires us to incur substantial costs and requires substantial management attention. In addition, our management team has limited experience managing a public company and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain additional executive management and qualified board members.

As a public company, we will incur substantial legal, accounting and other expenses that we did not incur as a private company. For example, we are subject to the reporting requirements of the Exchange Act, the applicable requirements of the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the rules and regulations of the SEC. The rules and regulations of NYSE American also apply to us. As part of the new requirements, we have established and will need to maintain effective disclosure and financial controls and have made and will need to maintain changes to our corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming or costly, and increase demand on our systems and resources.

We are leanly staffed and some of our management and other key personnel have limited experience managing a public company and preparing public filings. In addition, as a public company, certain of our management and other key personnel will be required to divert attention from other business matters to devote substantial time to the reporting and other requirements of being a public company. In particular, we expect to incur significant expense and devote substantial management effort to complying with the requirements of Section 404 of the Sarbanes-Oxley Act. We will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

As a result of disclosure of information in this Report and in filings required of a public company, our business and financial condition will become more visible, which may result in threatened or actual litigation, including by stockholders and competitors. If such claims are successful, our business and operating results could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and operating results.

In addition, as a result of our disclosure obligations as a public company, we have reduced flexibility and are under pressure to focus on short-term results, which may adversely affect our ability to achieve long-term profitability.

## Item 1B. Unresolved Staff Comments

Not applicable.

## **Item 1C. Cybersecurity**

We maintain a cybersecurity risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats and to protect the confidentiality, integrity, and availability of our critical systems and information.

The underlying process and controls of our cyber risk management program incorporate recognized best practices and standards for cybersecurity and information technology ("IT"), including the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). We have an annual risk assessment performed by a third-party specialist of our cyber risk management program against the NIST CSF. This assessment identifies, quantifies, and categorizes material cyber risks. In addition, the Company, in conjunction with our third-party specialists, have developed a risk mitigation plan to address such risks, and where necessary, to remediate potential vulnerabilities identified through the assessment process.

We maintain policies and processes over areas such as information security, IT asset lifecycle, data destruction, backup, access provisioning, and maintenance of network accounts, to help govern the processes put in place by management designed to protect our IT assets, data, and services from threats and vulnerabilities. We partner with cybersecurity providers and consultants (collectively, "providers") leveraging third-party technology and expertise. These providers are a key part of our cybersecurity risk management strategy and infrastructure. These providers deliver services including systems inventory monitoring, vulnerability testing, user management including restricted access of privileged accounts, capacity monitoring, network protection and monitoring, endpoint protection, managed detection and response, remote monitoring and management, cybersecurity user awareness training, data backup management, incident response, cybersecurity strategy, and cyber risk advisory, assessment, and remediation.

Our management team, in conjunction with our third-party IT and cybersecurity service providers, is responsible for oversight and administration of our cyber risk management program, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Our management team, in conjunction with our strategic third-party partners, oversees our cybersecurity technologies, initiatives, and processes, and relies on threat intelligence as well as other information obtained from governmental, public, or private sources, including external consultants engaged for strategic cyber risk management, advisory and decision making.

We have implemented third-party risk management processes to manage the risks associated with reliance on vendors, critical service providers, and other third-parties that may lead to a service disruption or an adverse cybersecurity incident. This includes an assessment of vendors during the selection and onboarding process, review of System and Organization Control (SOC) reports on an annual basis and a regular review of vendor contracts.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. We acknowledge that the risk of cyber incidents is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of business. The Company has not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, financial condition, results of operations, or cash flows. We proactively seek to detect and investigate unauthorized attempts and attacks against IT assets, data, and services, and to prevent their occurrence and recurrence where practicable; however, potential vulnerabilities to known or unknown threats will still remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject the Company to additional liability and reputational harm. In response to such risks, we have implemented initiatives such as implementation of the cybersecurity risk assessment process and development of an incident response plan.

For more information, see the section titled "Risk Factor—Our business and operations would suffer in the event of computer system failures, including but not limited to our information technology systems, infrastructure and data, or those of our third-party vendors, contractors or consultants failing, becoming unavailable, or suffering security breaches, losses or leakages of data and other disruptions, which could result in disruption of our services, compromise sensitive information (including personal information) related to our business, or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business."

## **Cybersecurity Governance**

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (the "Committee") oversight of cybersecurity, data privacy and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program and cybersecurity risk exposures, and the steps taken by management to monitor and mitigate cybersecurity risks. The Committee is composed of members of our board of directors with diverse expertise, including risk management, biotechnology, chief executive officer and chief financial officer roles, and multiple public company directorships, which has prepared them to oversee our cybersecurity risks.

The Committee receives periodic reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the Board regarding its activities, including those related to cybersecurity. The Board also receives briefings from management on our cybersecurity risk management program. Board members receive presentations on cybersecurity topics from our Chief Executive Officer and EVP, Chief Legal Officer, internal security consultants and external experts as part of the Board's continuing education on topics that impact public companies.

Our management team, including our Chief Executive Officer and EVP, Chief Legal Officer, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises efforts to prevent, detect, mitigate and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security consultants; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment. Our management team's experience includes monitoring the cybersecurity landscape for new risks and best practices, developing and executing cybersecurity strategies, overseeing related governance policies, testing compliance with applicable technical standards, remediating known risks and leading employee training programs.

## **Item 2. Properties**

Our principal executive office is located at 5 Park Plaza, Suite 1750, Irvine, California 92614. In September 2021, we entered into a lease agreement for 8,000 square feet of office space located at this facility, with a lease term of 36 months beginning in December 2021 and ending in December 2024. In March 2024, we entered into an amendment to extend the lease term for an additional 60 months to December 2029. We may look for additional or alternate space for our operations, and we believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

## **Item 3. Legal Proceedings**

On September 18, 2023, Odeon Capital Group LLC ("Odeon") filed a lawsuit against the Company in the Supreme Court of the State of New York, alleging that the Company failed to pay Odeon's deferred underwriting fee of \$1.25 million. Odeon claims that it served as the underwriter for Priveterra Acquisition Corp., the special purpose acquisition company with which Old AEON merged with and into in July 2023. Odeon seeks monetary damages for the full amount of its claimed underwriting fee, punitive damages, attorneys' fees and other amounts. In November 2023, the Company filed a motion to dismiss certain claims included in Odeon's complaint. In April 2024, the Company successfully obtained a dismissal of Odeon's non-breach of contract claims, including the tort claims, breach of covenant claim and associated punitive damages claim. Odeon's breach of contract claim is proceeding, with each party filing a summary judgment motion in March 2025, which the court is expected to decide upon in the coming months.

## **Item 4. Mine Safety Disclosures**

Not applicable.

#### PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity

#### **Market Information**

Our common stock trades on NYSE American under the symbol "AEON". Trading of our common stock commenced on July 24, 2023 in connection with the consummation of our Merger. Prior to that time, there was no established public trading market for our common stock.

#### Holders

As of March 17, 2025, there were approximately 461 holders of record of our common stock. These numbers do not include beneficial owners whose shares were held in street name. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

#### **Dividends**

The Company has never declared dividends on the Company's equity securities, and currently does not plan to declare dividends on shares of the Company's common stock in the foreseeable future. The Company expects to retain future earnings, if any, for use in the operation and expansion of the Company's business. The payment of cash dividends in the future, if any, will be at the discretion of the Board and will depend upon such factors as earning levels, capital requirements, overall financial condition and any other factors deemed relevant by the Board.

## **Unregistered Sales of Equity Securities and Use of Proceeds**

During the fiscal year ended December 31, 2024, the Company did not make any unregistered issuances or sales of equity securities that were not reported in a Current Report on Form 8-K.

## Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

#### Item 6. Reserved

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements and the related notes and other financial information included elsewhere in this Report. Some of the information contained in this discussion and analysis contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the sections of this Report captioned "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements", actual results may differ materially from those anticipated in these forward-looking statements. Unless the context otherwise requires, references to "we", "us", "our" and "the Company" refer to the business and operations of AEON Biopharma, Inc. and its consolidated subsidiaries prior to the Merger ("Old AEON" or the "Predecessor") and to AEON Biopharma, Inc. ("AEON") following the consummation of the Merger.

On December 12, 2022, Old AEON and Priveterra Acquisition Corp. ("Priveterra"), a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, or other similar business combination with one or more target businesses, entered into a Business Combination and Merger Agreement (the "Business Combination Agreement"). On July 21, 2023, the parties consummated the transactions contemplated by the Business Combination Agreement (collectively referred to as the "Merger"). In connection with the closing of the Merger (the "Closing"), Priveterra changed its name from Priveterra Acquisition Corp. to AEON Biopharma, Inc.

Priveterra was deemed the accounting acquirer in the Merger based on an analysis of the criteria outlined in Accounting Standards Codification 805, Business Combinations. Old AEON was deemed to be the predecessor entity based on an analysis of the criteria outlined in the Accounting Standards Codification 805, Business Combinations. Accordingly, the historical financial statements of Old AEON became the historical financial statements of the combined company upon the consummation of the Merger. As a result, the financial statements included in this report reflect (i) the historical operating results of Old AEON prior to the Merger; and (ii) the combined results of the Company following the Closing. The accompanying financial information includes a predecessor period, which includes the periods through July 21, 2023 concurrent with the Merger, and the successor period starting from July 22, 2023 through the date of this report. A black-line between the Successor and Predecessor periods has been placed in the consolidated financial statements and in the tables to the notes to the statements to highlight the lack of comparability between these two periods and differentiate the cut-off of these periods.

#### Overview

We are a clinical stage biopharmaceutical company focused on developing our botulinum toxin complex, prabotulinumtoxinA injection ("ABP-450"), for debilitating medical conditions, with an initial focus on the neurosciences market. We plan to develop and seek regulatory approval of ABP-450 as a biosimilar product in the United States through submission of a Biologics License Application, or BLA, under Section 351(k) of the Public Health Service Act, or a Section 351(k) BLA, with the goal of addressing the estimated \$3.0 billion global therapeutic botulinum toxin market, which is projected to grow to \$4.4 billion in 2027, according to the Decision Resources Group Therapeutic Botulinum Toxin Market Analysis Global as of 2021. ABP-450 is the same botulinum toxin complex that is currently approved as a biosimilar in Mexico and India and, in the U.S. is approved to provide temporary improvement in the appearance of moderate to severe glabellar lines for certain adult patients and marketed by Evolus, Inc. under the name Jeuveau in the United States and Nuceiva in Canada and the European Union. We have exclusive development and distribution rights for certain therapeutic uses of ABP-450 in the United States, Canada, the European Union, the United Kingdom, and certain other international territories. We have built a highly experienced management team with specific experience in biopharmaceutical and botulinum toxin development and commercialization.

We have completed a Phase 2 study of ABP-450 for the treatment of cervical dystonia and completed enrollment and dosing of patients for a Phase 2 double blind study of ABP-450 for the treatment of both chronic and episodic migraine. We originally intended to pursue a submission of a BLA under Section 351(a) of the Public Health Service Act, or an Original BLA, seeking one or more potential therapeutic indications for ABP-450. However, our Phase 2 clinical trials for episodic and chronic migraine did not meet their respective primary endpoints. In May 2024, we announced the discontinuation of our Phase 2 clinical trials for episodic and chronic migraine in order to implement certain cash preservation measures. On July 9, 2024, we announced a strategic reprioritization to pursue a 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product for all of the indications for which Botox is approved, other than the cosmetic uses (for which we do not hold development or commercialization rights).

We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies.

Botulinum toxins have proven to be a highly versatile therapeutic biologic, with over 230 potential therapeutic uses documented in published scientific literature and twelve approved therapeutic indications in the United States. Our initial development programs for ABP-450 were directed at migraine, cervical dystonia and gastroparesis. We selected these initial programs based on a comprehensive product assessment screen designed to identify indications where we believe ABP-450 has the potential to deliver significant value to patients, physicians and payors and where its clinical, regulatory and commercial characteristics suggest viability. We believe that ABP-450 has potential across a broad range of target indications and we plan to continue to explore additional development programs that satisfy our product assessment screens.

The FDA allowed our Investigational New Drug application, or IND, for ABP-450, supporting our clinical trials in the preventative treatment for migraine, to proceed in October 2020, and we began treating patients in our Phase 2 clinical study beginning in March 2021. Prior to commencing this Phase 2 study, no Phase 1 clinical studies of ABP-450 had been performed in regard to migraine by us or any other party. Nevertheless, given the extensive preclinical toxicology and other data developed by our licensing partner, Daewoong, and the aesthetic licensor of ABP-450, Evolus, the FDA permitted us to proceed directly to this Phase 2 clinical trial.

The FDA allowed our IND for ABP-450, which supports our clinical trials in cervical dystonia, to proceed in October 2020, and we began treating patients in our Phase 2 clinical study beginning in April 2021. We enrolled 59 patients in this randomized, double-blind, placebo-controlled study across approximately 20 study sites in the United States. Patients enrolled into the study received one of four different injection cycles, low dose of 150 units, mid-dose of 250 units, high dose of 350 units or placebo, with patients evenly split among the four arms. Topline data from the Phase 2 cervical dystonia study, released in September 2022, showed that ABP-450 met all primary endpoints and a number of other key secondary endpoints, supporting the further development of ABP-450 in reducing signs and symptoms associated with cervical dystonia. We may commence a Phase 3 study in cervical dystonia pending the results of the comparative analytical studies and discussions with the FDA in a Biological Product Development meeting.

We have never been profitable from operations and, as of December 31, 2024, we had an accumulated deficit of \$431.6 million. We have never generated revenue from ABP-450. We have concluded that we do not have sufficient cash to fund our operations for 12 months from the date of our financial statements without additional financing, and as a result, there is substantial doubt about our ability to continue as a going concern. As of the date of this Report, we have sufficient cash to fund our operating plan into the fourth quarter of 2025. Any further development of ABP-450 for any indication, including the biosimilar pathway and any additional studies in cervical dystonia, will require additional funding, which may not be available to us on reasonable terms, or at all.

We do not expect to receive any revenue from ABP-450 or any future product candidates that we develop unless and until we obtain regulatory approval and commercialize ABP-450 or any future product candidates. We expect to continue to incur significant expenses and increasing net operating losses for the foreseeable future as we seek regulatory approval, prepare for and, if approved, proceed to commercialization of ABP-450.

## Liquidity and Capital Resources and Going Concern

As disclosed further below in the section titled "Liquidity and Capital Resources", we have incurred operating losses and negative cash flows from operating activities since inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2024 (Successor), we had reported cash and cash equivalents of \$13 thousand and an accumulated deficit of \$431.6 million. As a result of these conditions, management has concluded that substantial doubt about our ability to continue as a going concern exists as conditions and events, considered in the aggregate, indicate that it is probable that we will be unable to meet our obligations as they become due within one year after the date that the financial statements included in this Report are issued. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our business plans and secure sources of financing and ultimately attain profitable operations.

## **Notice of Noncompliance**

On February 3, 2025, the Company received a written notice of non-compliance (the "Notice") from the NYSE American LLC (the "NYSE American") stating that the Company is not in compliance with continued listing standards of Section 1003(a)(i) of the NYSE American Company Guide (the "Company Guide"), which requires stockholders' equity of \$2.0 million or more if the listed company has reported losses from continuing operations and/or net losses in two of its three most recent fiscal years (the "Minimum Requirement"), as defined in Section 1003(a)(i) of the Company Guide. Pursuant to the Notice, the Company reported a stockholders' deficit of \$32.1 million at September 30, 2024 and has had losses in the two most recent fiscal years ended December 31, 2023 based on the Company's Annual Report on Form 10-K/A filed with the U.S. Securities and Exchange Commission on May 14, 2024, and the Company is not currently eligible for any exemption from the stockholders' equity requirement in Section 1003(a) of the Company Guide, and as such, the NYSE American deems the Company below compliance with the Minimum Requirement.

The Notice has no immediate effect on the listing of the Company's listing on the NYSE American. The Company has been provided with a compliance period of 18 months to regain compliance with the Minimum Requirement. To regain compliance, the Company must submit a plan by March 5, 2025, with which the Company has complied, advising of actions taken or will be taken to regain compliance with the continued listings standards of the Company Guide by August 3, 2026 (the "Plan"). The Plan will be subject to approval and periodic reviews by the NYSE American to monitor compliance with the Plan. If the Plan is not accepted, or if the Plan is accepted but the Company is not in compliance with the Minimum Requirement by August 3, 2026, or if the Company does not make progress consistent with the Plan, then the NYSE American will initiate delisting proceedings as appropriate. The Company intends to consider available options to resolve the non-compliance with the Minimum Requirement by August 3, 2026. However, there can be no assurance that the Company will be able to regain compliance with the Minimum Requirement.

## **Convertible Note Subscription**

On March 19, 2024, we entered into the Subscription Agreement with Daewoong relating to our sale and issuance of the Convertible Notes in the principal amount of up to \$15.0 million, which are convertible into shares of common stock, subject to certain conditions and limitations set forth in each Convertible Note. Each Convertible Note contains customary events of default, accrues interest at an annual rate of 15.79% and has a maturity date that is three years from the funding date (the "Maturity Date"), unless earlier repurchased, converted or redeemed in accordance with its terms prior to such date. We will use the net proceeds from each Convertible Note to support the late-stage clinical development of ABP-450 and for general working capital purposes. Pursuant to the terms of the Subscription Agreement, on March 24, 2024, we issued and sold to Daewoong one Convertible Note in the principal amount of \$5.0 million and, on April 12, 2024, we issued and sold to Daewoong an additional Convertible Note in the principal amount of \$10.0 million.

On March 19, 2024, we entered into a Fourth Amendment to the License Agreement (the "License Agreement Amendment") with Daewoong, which amends that certain License and Supply Agreement, by and between us and Daewoong, dated December 20, 2019, as amended on July 29, 2022, January 8, 2023 and April 24, 2023 (the "License Agreement"). Pursuant to the terms of the License Agreement Amendment, the License Agreement will terminate if, over any six-month period, (a) we cease to commercialize ABP-450 in certain territories specified in the License Agreement and (b) we cease to advance any clinical studies of ABP-450 in such territories. The License Agreement Amendment also provides that, in the event that the License Agreement is terminated for the foregoing reasons, Daewoong will have the right to purchase all Know-How (as defined in the License Agreement) related to ABP-450 for a price of \$1.00 (the "Termination Purchase Right"). The Termination Purchase Right will terminate and expire upon Daewoong's sale of 50% of its common stock, including common stock held by its affiliates and common stock that would be issued upon an Automatic Conversion or Optional Conversion (as defined below).

If, prior to the Maturity Date, the Company consummates a bona-fide third-party financing in the form of Common Stock or any securities convertible into, or exchangeable or exercisable for, Common Stock (subject to certain exceptions as described in each Convertible Note), in one or more transactions or a series of related and substantially similar and simultaneous transactions at the same purchase price from third parties unaffiliated with Daewoong and its affiliates, for aggregate gross cash proceeds to the Company of at least \$30.0 million (a "Qualified Financing"), then, upon written notice thereof to Daewoong by the Company, on the closing date of such Qualified Financing, each Convertible Note will automatically convert in whole (the "Automatic Conversion") (subject to any limitations under the rules and regulations of NYSE American), without any further action by Daewoong, into a number of shares equal to: (i) one and three tenths (1.3) multiplied by (ii) the quotient of (a) the principal amount of each Convertible

Note and all accrued and unpaid interest to be converted divided by (b) the per share price of the common stock sold in the Qualified Financing, provided that such per share price of common stock is at least \$1.00 per share.

If, prior to the Maturity Date, the Company provides (i) written notice to Daewoong that it has publicly announced topline clinical data regarding its Phase 3 clinical study of ABP-450 for the treatment of chronic or episodic migraine, and such data indicates achievement of all primary endpoints or (ii) a written notice that the Company has consummated a Change of Control (as defined in each Convertible Note), Daewoong will have the right for thirty (30) days following receipt of either such notice, at Daewoong's option (the "Optional Conversion"), to convert all (but not less than all) of the remaining outstanding portion of each Convertible Note (subject to any limitations under the rules of NYSE American) into an amount of shares of common stock equal to: (i) one and three tenths (1.3) multiplied by (ii) the quotient of (a) the principal amount of each Convertible Note and all accrued and unpaid interest to be converted divided by (b) the volume weighted average trading per share price of common stock over the five (5) trading days prior to the Company's receipt of Daewoong's written notice of exercise of the Optional Conversion, provided that such per share price of common stock is at least \$1.00 per share.

## **Public Offering**

On January 6, 2025, we entered into an underwriting agreement (the "Underwriting Agreement") with Aegis Capital Corp. ("Aegis" or the "Underwriter") pursuant to which the Company agreed to sell and issue, in an underwritten public offering (the "Offering") 555,571 Common Units, each consisting of (i) one (1) share of Common Stock, (ii) one (1) Series A Registered Common Warrant to purchase one (1) share of Common Stock per warrant at an exercise price of \$45.00 (the "Series A Warrants") and (iii) one (1) Series B Registered Common Warrant to purchase one (1) share of Common Stock per warrant at an exercise price of \$45.00 (the "Series B Warrants" and together with the Series A Warrants, the "Warrants"). Additionally, the Company granted Aegis a 45-day option to purchase additional shares of Common Stock and/or Warrants of (i) up to 15.0% of the number of shares of Common Stock sold in the offering, (ii) up to 15.0% of the number of Series A Warrants sold in the offering and (iii) up to 15.0% of the number of Series B Warrants sold in the offering. The purchase price per additional share of Common Stock is equal to the public offering price of one Common Unit (less \$0.01 allocated to each full Warrant), less the underwriting discount. The purchase price per additional Warrant is \$0.01. On January 7, 2025, Aegis exercised its over-allotment option with respect to 83,334 Series A Warrants and 83,334 Series B Warrants.

The closing of the Offering occurred on January 7, 2025. The Company received net proceeds of approximately \$18.3 million from the Offering, after deducting the offering expenses payable by the Company, including the Underwriter's fees and expenses. The Company intends to use the net proceeds from the Offering for general corporate purposes, including working capital.

As of March 21, 2025, approximately 89.15% of the Series B Warrants, which can be exercised on a cashless three-shares-perwarrant basis, have been exercised.

As a result of becoming a public company, we will need to engage additional resources and/or hire additional staff and implement processes and procedures to address public company regulatory requirements and customary practices. We expect to incur additional annual expenses for, among other things, directors' and officers' liability insurance, director fees and additional internal and external accounting, legal and administrative resources and fees.

## **Reverse Stock Split**

On February 24, 2025, following the Special Meeting of Shareholders, the Board approved the filing of a Certificate of Amendment to the Certificate of Incorporation (the "Charter Amendment") to effect a reverse stock split at a split ratio of 1-for-72 (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each 72 pre-split shares of Common Stock outstanding will automatically combine into one new share of Common Stock without any action on the part of the holders. The Reverse Stock Split will affect all of the Company's stockholders uniformly and will not affect any stockholder's percentage ownership interests in the Company. No fractional shares will be issued in connection with the Reverse Stock Split. In lieu of fractional shares, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the reclassification and combination following the effective time of the Reverse Stock Split (after taking into account all fractional shares of Common Stock otherwise issuable to such holder) shall instead receive a number of shares rounded up to the nearest whole share. Proportional adjustments will be made to the number of shares of Common Stock issuable upon exercise or conversion of the Company's outstanding equity awards and warrants, as well as the applicable exercise price, except in cases where the applicable agreement provides otherwise.

On February 26, 2025, the effective date of the Reverse Stock Split, the number of outstanding shares of Common Stock was reduced from approximately 79.9 million shares to approximately 1.1 million shares (subject to rounding of fractional shares, which will be rounded up to the nearest whole share). The capital stock accounts, all share data and earnings (loss) per share, restricted stock units and stock options and corresponding exercise price give effect to the reverse stock split, applied retrospectively, to all periods presented for Successor and on-the-line periods. However, share amounts and per share data for the Predecessor have not been adjusted to reflect our 1-for-72 reverse stock split because the capital structure of Predecessor is not comparable to the Successor.

### **Components of Our Results of Operations**

#### Revenue

We have generated no revenue from the sale of products and do not anticipate deriving any product revenue unless and until we receive regulatory approval for, and are able to successfully commercialize, ABP-450.

## **Operating Expenses**

Selling, General and Administrative Expenses

Selling, general and administrative expenses ("SG&A") expenses, consist primarily of compensation for personnel, including stock-based compensation, management, finance, legal, and regulatory functions. Other SG&A expenses include travel expenses, market research and analysis, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses, and allocated facilities-related expenses. We anticipate that our SG&A expenses will increase in the future to support our continued research and development ("R&D"), activities. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of the NYSE American and the SEC, insurance, and investor relations costs. We expect to incur increased costs associated with establishing sales, marketing, and commercialization functions in advance of potential future regulatory approvals and commercialization of our product candidates. If ABP-450 obtains United States regulatory approval for any indication, we expect that we would incur significantly increased expenses associated with building a sales and marketing team and funding commercial activities.

## Research and Development Expenses

Our R&D expenses are primarily attributed to the development of ABP-450 for migraine, cervical dystonia and gastroparesis. Due to the stage of our development and our ability to use resources across all of our programs, most of our R&D costs are not recorded on a program-specific basis. We expect our R&D expenses to continue to increase as we, subject to raising additional capital, develop and seek regulatory approval of ABP-450 as a biosimilar product in the United States through a Section 351(k) BLA, using AbbVie Inc.'s product Botox as a proposed reference product for all of the indications for which Botox is approved, other than the cosmetic uses (for which we do not hold development or commercialization rights), which may include initiating a Phase3 study of ABP-450 in cervical dystonia. R&D expenses associated with these activities may include third-party costs such as expenses incurred under agreements with CROs, the cost of consultants who assist with the development of ABP-450 on a program-specific basis, investigator grants, sponsored research, product costs in connection with acquiring ABP-450 from Daewoong and Botox for use in conducting preclinical and clinical studies, and other third-party expenses attributable to the development of our product candidates.

R&D activities will be critical to achieving our business strategy. The biosimilar pathway will require greater costs in the beginning stages in order to procure the necessary toxin for the analytical studies. Any clinical studies, such as Phase 3 for cervical dystonia, we will generally incur greater development costs than those programs incurred in the earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical studies. We expect our R&D expenses to be significant over the next years as we pursue the development of ABP-450 as a biosimilar and seek regulatory approval using Botox as the reference product. As a result, we are unable to determine the duration and completion costs of our programs or when and to what extent we will generate revenue from commercialization and sale of any of our product candidates. Our R&D activities may be subject to change from time to time as we evaluate our priorities and available resources.

Acquired in-Process Research and Development

The Company records costs incurred in obtaining technology licenses to research and development expense as acquired inprocess research and development ("IPR&D") if the technology licensed has not reached technological feasibility and has no alternative future use. The acquired IPR&D recorded at the Closing was written off to the Successor's consolidated statement of operations for the period ended December 31, 2023.

## Change in Fair Value of Contingent Consideration

The Company determined that the Contingent Consideration would be classified as a liability on the Successor's consolidated balance sheets and remeasured at each reporting period with changes to fair value recorded to the Successor's consolidated statements of operations and comprehensive income (loss).

## Other Income (Loss), Net

Other loss, net primarily consists of gains and losses resulting from the remeasurement of the fair value of our convertible notes, forward purchase agreements, warrant liabilities, each described below, at each balance sheet date.

Change in fair value of convertible notes – The Company elected the fair value option to account for its convertible notes, with the subsequent changes in fair value recorded in the consolidated statement of operations and comprehensive income (loss).

Loss on embedded forward purchase agreement and make whole derivative - the Company has determined that each of its forward purchase agreements entered in connection with the Merger is a freestanding hybrid financial instrument comprising a subscription receivable and embedded features, which were bifurcated and accounted for separately as derivative instruments. The Company recorded the derivatives as liabilities and measured them at fair value with the initial value of the derivative recorded as a loss "on the line" in the Successor's opening accumulated deficit. On the line describes those transactions triggered by the consummation of the Merger that are not recognized in the consolidated financial statements of the Predecessor or the Successor as they are not directly attributable to either period but instead were contingent on the Merger. Subsequent changes in the bifurcated derivatives are recorded in the Successor's consolidated statements of operations and comprehensive income (loss). Upon termination of the forward purchase agreements in the second quarter of fiscal 2024, the Company recorded a charge to the consolidated statement of operations of \$20.3 million to reverse the related subscription receivable and derivative liability on the accompanying consolidated balance sheet.

Change in fair value of warrants - Changes in the estimated fair value of our warrant liabilities are recognized as a non-cash gain or loss on the Successor's consolidated statements of operations and comprehensive income (loss).

## **Results of Operations**

The following table summarizes our results of operations for the periods indicated (in thousands):

		Year Ended	
		December 31	,
	2024	2023	2023
		Successor	Predecessor
	~	July 22 to	January 1 to
	Successor	December 31	<b>July 21</b>
Operating expenses:			
Selling, general and administrative	\$ 13,643	\$ 9,949	\$ 9,841
Research and development	14,181	13,243	19,803
Acquired in-process research and development		348,000	_
Change in fair value of contingent consideration	(100,809)	(52,750)	
Total operating costs and expenses	(72,985)	318,442	29,644
Income (loss) from operations	72,985	(318,442)	(29,644)
Other income (loss):			
Change in fair value of convertible notes	3,311	_	(19,359)
Change in fair value of warrants	(14,719)	2,318	
Loss on embedded forward purchase agreements			
and derivative liabilities, net	(19,667)	(8,366)	(11,789)
Other income, net	95	536	114
Total other loss, net	(30,980)	(5,512)	(31,034)
Income (loss) before taxes	42,005	(323,954)	(60,678)
Income taxes			
Net income (loss)	\$ 42,005	\$ (323,954)	\$ (60,678)
Basic net income (loss) per share	\$ 77.74	\$ (627.33)	\$ (0.44)
Diluted net income (loss) per share	\$ 72.93	\$ (627.33)	\$ (0.44)
Weighted average shares of common stock			
outstanding used to compute basic net income (loss)			
per share	540,360	516,404	138,848,177
Weighted average shares of common stock			
outstanding used to compute diluted net income			
(loss) per share	575,945	516,404	138,848,177
• • • •			•

Comparison of the year ended December 31, 2024 (Successor) to the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor)

Operating Expenses

Selling, General and Administrative (SG&A) Expenses

SG&A expenses were \$13.6 million for the year ended December 31, 2024 (Successor), a decrease of \$6.1 million, or 31%, compared to \$9.8 million and \$9.9 million for the period from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), respectively. The decrease in SG&A expenses was primarily attributable to a decrease of \$4.4 million in legal expenses and professional fees related to the Merger, \$1.1 million of stock-based compensation expense, of which \$0.9 million is related to the repricing of stock options in connection with the Merger, and \$0.5 million in payroll-related expenses due to FTE reduction in May 2024 following the strategic reprioritization to the biosimilar pathway.

## Research and Development (R&D) Expenses

R&D expenses were \$14.2 million for the year ended December 31, 2024 (Successor), a decrease of \$18.9 million, or 57%, compared to \$19.8 million and \$13.2 million for the period from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), respectively. The decrease was primarily attributable to \$18.5 million reduction in R&D expenses due to wind down of Phase 2 cervical dystonia in 2023 and close out of Phase 2 clinical trials for the migraine programs in mid-2024.

## Change in Fair Value of Contingent Consideration

The Company recognized a gain of \$100.8 million for the year ended December 31, 2024 (Successor), an increase of \$48.1 million, or 91%, compared to \$52.8 million related to the change in the fair value of the contingent consideration liability for the period from July 22, 2023 to December 31, 2023 (Successor). See Note 6 Fair Value Measurements to the consolidated financial statements for further discussion. The gain of \$100.8 million for the year ended December 31, 2024 is primary due to the changes in probabilities of meeting milestones and fluctuations in stock price from \$518.40 at December 31, 2023 to \$38.88 at December 31, 2024, as compared to the gain of \$52.8 million for the period ended December 31, 2023, which was primarily due to decrease in stock price used in the initial valuation of \$780.48 to \$518.40 at December 31, 2023.

## Other Loss, Net

Other loss, net was \$31.0 million for the year ended December 31, 2024, a decrease of \$5.6 million, or 15%, compared to \$31.0 million and \$5.5 million for the period from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), respectively. The change is primarily due to a gain of \$3.3 million for the year ended December 31, 2024 (Successor) compared to a loss of \$19.4 million for the period from January 1, 2023 to July 21, 2023 (Predecessor) related to changes in fair value of convertible notes, offset by a loss on change in fair value of warrants of \$14.7 million for the year ended December 31, 2024, compared to a gain of \$2.3 million on change in fair value of warrants for the period from July 22, 2023 to December 31, 2023 (Successor).

## **Liquidity and Capital Resources**

Our primary sources of capital have been debt financing (Predecessor) and equity financing (Successor). We have experienced recurring losses from operations and have a net capital deficiency and negative cash flows from operations since our inception. As of December 31, 2024 (Successor), we had reported cash and cash equivalents of \$13 thousand and an accumulated deficit of \$431.6 million.

On May 3, 2024, we announced preliminary top-line results from its planned interim analysis of the Phase 2 trial with ABP-450 in the preventative treatment of chronic migraine, which did not meet the primary or secondary endpoints. We originally intended to pursue submission of an Original BLA seeking one or more potential therapeutic indications for ABP-450. However, in May 2024, we announced the discontinuation of our Phase 2 clinical trials for episodic and chronic migraine in order to implement certain cash preservation measures. On July 9, 2024, we announced a strategic reprioritization to pursue a 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product for all of the indications for which Botox is approved, other than the cosmetic uses.

On March 19, 2024, we entered into the Subscription Agreement with Daewoong relating to our sale and issuance of Convertible Notes in the principal amount of up to \$15.0 million, which are convertible into shares of common stock, subject to certain conditions and limitations set forth in each Convertible Note. Each Convertible Note will contain customary events of default, will accrue interest at an annual rate of 15.79% and will have a maturity date that is three years from the funding date, unless earlier repurchased, converted or redeemed in accordance with its terms prior to such date. We will use the net proceeds from each Convertible Note to support the late-stage clinical development of ABP-450 and for general working capital purposes. Pursuant to the terms of the Subscription Agreement, on March 24, 2024, the Company issued and sold to Daewoong one Convertible Note in the principal amount of \$5.0 million, and on April 12, 2024, the Company issued and sold to Daewoong one Convertible Note in the principal amount of \$10.0 million.

On March 19, 2024, we entered into the License Agreement Amendment with Daewoong, which amends the License Agreement. Pursuant to the terms of the License Agreement Amendment, the License Agreement will terminate if, over any six-month period, (a)

we cease to commercialize ABP-450 in certain territories specified in the License Agreement and (b) we cease to advance any clinical studies of ABP-450 in such territories. The License Agreement Amendment also provides that, in the event that the License Agreement is terminated for the foregoing reasons, Daewoong will have the right to purchase all Know- How (as defined in the License Agreement) related to ABP-450 for a price of \$1.00. The Termination Purchase Right will terminate and expire upon Daewoong's sale of 50% of its common stock, including common stock held by its affiliates and common stock that would be issued upon an Automatic Conversion or Optional Conversion (as defined in the Convertible Notes).

On July 9, 2024, we announced a strategic reprioritization to pursue a Section 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product. We held an initial meeting with the FDA in the third quarter of 2024 during which we aligned with the FDA on next steps to develop a Botox biosimilar. We commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA in the second half of 2025 to review the results from the studies. However, the commencement of studies, preparation for the potential BPD meeting and any further development of ABP-450 would require additional funding in the form of equity financings or debt. There can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be commercially acceptable. Furthermore, the use of equity as a source of financing would dilute existing shareholders.

On January 6, 2025, we entered into an underwriting agreement with Aegis pursuant to which we agreed to sell and issue, in an underwritten public offering (the "Offering") 555,571 Common Units, each consisting of (i) one (1) share of Common Stock, (ii) one (1) Series A Registered Common Warrant to purchase one (1) share of Common Stock per warrant at an exercise price of \$45.00 (the "Series A Warrants") and (iii) one (1) Series B Registered Common Warrant to purchase one (1) share of Common Stock per warrant at an exercise price of \$45.00 (the "Series B Warrants" and together with the Series A Warrants, the "Warrants"). Additionally, the Company granted Aegis a 45-day option to purchase additional shares of Common Stock and/or Warrants of (i) up to 15.0% of the number of shares of Common Stock sold in the offering, (ii) up to 15.0% of the number of Series A Warrants sold in the offering and (iii) up to 15.0% of the number of Series B Warrants sold in the offering. The purchase price per additional share of Common Stock is equal to the public offering price of one Common Unit (less \$0.01 allocated to each full Warrant), less the underwriting discount. The purchase price per additional Warrant is \$0.01. On January 7, 2025, Aegis exercised its over-allotment option with respect to 83,334 Series A Warrants and 83,334 Series B Warrants. The Offering closed on January 7, 2025, and the Company received net proceeds of approximately \$18.3 million from the Offering, after deducting the offering expenses payable by the Company, including the Underwriter's fees and expenses.

As of the date of this Report, we expect to have sufficient cash to fund our operating plan into the fourth quarter of 2025. We will actively attempt to secure additional capital to fund our operations. However, we cannot assure you that we will be able to raise additional capital on commercially reasonable terms or at all.

We have incurred operating losses and negative cash flows from operating activities since inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. Our primary use of cash is to fund operating expenses, which consist of R&D expenditures, including clinical trials, as well as SG&A expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses. We expect to continue to incur substantial costs in order to conduct R&D activities necessary to develop and commercialize our product candidates. Until such time, if ever, as we can generate substantial product revenue from sales of ABP-450, we will need additional capital to undertake these activities and commercialization efforts, and, therefore, we intend to raise such capital through the issuance of additional equity, borrowings, and potentially strategic alliances with other companies. However, if such financing is not available at adequate levels or on acceptable terms, we could be required to reduce the scope of or eliminate some of our development programs or commercialization efforts, outlicense intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish these plans and secure sources of financing and ultimately attain profitable operations.

We may also seek to raise additional capital through the sale of public or private equity or convertible debt securities. If we incur additional debt, the debt holders would have rights senior to holders of common stock to make claims on our assets, and the terms of any debt could restrict our operations, including our ability to pay dividends to holders of our common stock. If we undertake discretionary financing by issuing equity securities or convertible debt securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at a price per share that is less than the price per share paid by current public stockholders. If we sell common stock, convertible securities, or other equity

securities in more than one transaction, stockholders may be further diluted by subsequent sales. Additionally, future equity financings may result in new investors receiving rights superior to our existing stockholders. Because our decision to issue securities in the future will depend on numerous considerations, including factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future issuances of debt or equity securities. As a result, our stockholders bear the risk of future issuances of debt or equity securities reducing the value of our common stock and diluting their interests.

We may receive additional capital from the cash exercise of the Private Placement Warrants. However, the exercise price of our Private Placement Warrants is \$828.00 per warrant and the last reported sales price of our common stock on March 17, 2025 was \$0.73. The likelihood that holders of the Private Placement Warrants will exercise their Private Placement Warrants, and therefore the likelihood of any amount of cash proceeds that we may receive, is dependent upon the trading price of our common stock after effectiveness of the registration statement related thereto registering the issuance of common stock underlying the Private Placement Warrants. If the trading price for our common stock does not maintain a price above \$828.00 per share, we do not expect holders to exercise their Warrants for cash. We will have broad discretion over the use of any proceeds from the exercise of such securities. Any proceeds from the exercise of such securities would increase our liquidity, but we are not currently budgeting for any cash proceeds from the exercise of the Private Placement Warrants when planning for our operational funding needs. The Private Placement Warrants may be exercised on a cashless basis at any time and we will not receive any proceeds from such exercise, even if the Private Placement Warrants are in-the-money.

To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product licenses on terms that may not be favorable to us. If these sources are insufficient to satisfy our liquidity requirements, we will seek to raise additional funds through future equity or debt financings. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. There can be no assurance that our efforts to procure additional financing will be successful or that, if they are successful, the terms and conditions of such financing will be favorable to us or our stockholders. If we are unable to raise additional financing when needed, we may be required to delay, reduce, or terminate the development, commercialization and marketing of our products and scale back our business and operations.

As a result of these conditions, management has concluded that substantial doubt about our ability to continue as a going concern exists as conditions and events, considered in the aggregate, indicate that it is probable that we will be unable to meet our obligations as they become due within one year after the date that the financial statements included in this Report are issued. Our financial information throughout this Report and our financial statements included elsewhere in this Report have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. This financial information and our consolidated financial statements do not include any adjustments that may result from an unfavorable outcome of this uncertainty. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our business plans and secure sources of financing and ultimately attain profitable operations.

## **Net Cash Used in Operating Activities**

Net cash used in operating activities for the year ended December 31, 2024 (Successor) was \$20.3 million, consisting primarily of a net income of \$42.0 million (Successor) and non-cash charges of \$(63.0) million, consisting primarily of \$(100.8) million related to change in fair value of contingent consideration (Successor) and \$(3.3) million related to the change in fair value of the convertible notes (Successor), offset by \$19.7 million related to loss on forward purchase agreement and derivative liabilities (Successor), \$14.7 million related to change in fair value of warrants (Successor) and \$6.3 million non-cash expense related to stock-based compensation for our executives and directors (Successor); and an increase in accounts payable of \$2.5 million and a decrease in accrued expenses and other liabilities of \$1.4 million due to timing of payments.

Net cash used in operating activities for the period from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor) were \$21.7 million and \$26.1 million, respectively, consisting primarily of a net losses of \$60.7 million (Predecessor) and \$324.0 million (Successor), respectively, and non-cash charges of \$34.4 million (Predecessor) and \$305.1 million (Successor), consisting primarily of \$348.0 million (Successor) write off of acquired IR&D, \$19.4 million related to the change in fair value of the convertible notes (Predecessor), \$11.8 million (Predecessor) and \$8.4 million (Successor) related to change in fair value of derivatives and \$3.2 million (Predecessor) and \$3.8 million (Successor) non-cash expense related to stock-based compensation for our executives and directors, offset by \$(52.8) million related to change in fair value of contingent consideration

(Successor) and \$(2.3) million related to change in fair value of warrants (Successor); and a decrease in accounts payable of \$4.6 million related to timing of payments to our vendors, offset by an increase in accrued expenses and other liabilities of \$2.5 million primarily related to increase in clinical trial accrual of \$3.0 million.

## **Cash Flows from Investing Activities**

There was no cash used in investing activities for the year ended December 31, 2024 and the period from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor).

## **Cash Flows from Financing Activities**

Net cash provided by financing activities for the year ended December 31, 2024 (Successor) and the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor) were \$15.1 million, \$14.0 million and \$0, respectively, primarily related to the issuance of convertible notes.

### Contingent Consideration

As part of the Merger, Founder Shares and certain Participating Stockholders shares (together, "Contingent Consideration Shares"), as further discussed below, contain certain contingent provisions.

On April 27, 2023, Priveterra and Old AEON amended the Business Combination Agreement. Concurrently with the amendment to the Business Combination Agreement, Priveterra amended the Sponsor Support Agreement to include restriction and forfeiture provisions related to the Founder Shares. In addition following the Closing, certain AEON stockholders will be issued a portion of up to 222,653 additional shares of common stock

Pursuant to the terms of the Sponsor Support Agreement, as amended, effective immediately after the Closing, 50% of the Founder Shares (i.e., 47,921 Founder Shares) (the "Contingent Founder Shares") were unvested and subject to the restrictions and forfeiture provisions set forth in this Sponsor Support Agreement. The remaining 50% of the Founder Shares and 100% of the Private Placement Warrants are not subject to such restrictions and forfeiture provisions. The Contingent Founder Shares shall vest, and shall become free of the provisions as follows:

- 13,890 of the Contingent Founder Shares (the "Migraine Phase 3 Contingent Founder Shares") shall vest upon the achievement of the conditions for the issuance of the Migraine Phase 3 Contingent Consideration Shares on or prior to the Migraine Phase 3 Outside Date;
- 13,890 of the Contingent Founder Shares (the "CD BLA Contingent Founder Shares") shall vest upon the achievement of the conditions for the issuance of the CD BLA Contingent Consideration Shares on or prior to the CD BLA Outside Date; and
- 20,141 of the Contingent Founder Shares (the "Episodic/Chronic Migraine Contingent Founder Shares") shall vest upon the earlier of (x) the achievement of the conditions for the issuance of the Episodic Migraine Contingent Consideration Shares on or before the Episodic Migraine Outside Date and (y) the achievement of the conditions for the issuance of the Chronic Migraine Contingent Consideration Shares on or before the Chronic Migraine Outside Date.

The Sponsor has agreed not to vote the Contingent Founder Shares during any period of time that such Contingent Founder Shares are subject to vesting.

Following the Closing, in addition to the consideration received at the Closing and as part of the overall consideration paid in connection with the Merger, certain holders of common stock in Old AEON (the "Participating AEON Stockholders") will be issued a portion of up to 222,653 additional shares of common stock, as follows:

- 13,996 shares of common stock, in the aggregate, if, on or before June 30, 2025 (as it may be extended, the "Migraine Phase 3 Outside Date"), the Company shall have commenced a Phase 3 clinical study for the treatment of chronic migraine or episodic migraine, which Phase 3 clinical study will have been deemed to commence upon the first subject having received a dose of any product candidate that is being researched, tested, developed or manufactured by or on behalf of the Company or any of its subsidiaries (any such product candidate, a "Company Product") in connection with such Phase 3 clinical study (such 13,996 shares of common stock, the "Migraine Phase 3 Contingent Consideration Shares"); and
- 55,659 shares of common stock, in the aggregate, if, on or before November 30, 2026 (as it may be extended, the "CD BLA Outside Date"), the Company shall have received from the FDA acceptance for review of the BLA submitted by the Company for the treatment of cervical dystonia (such 55,659 shares of common stock, the "CD BLA Contingent Consideration Shares");
- 55,659 shares of common stock, in the aggregate, if, on or before June 30, 2029 (as it may be extended, the "Episodic Migraine Outside Date"), the Company shall have received from the FDA acceptance for review of the BLA submitted by the Company for the treatment of episodic migraine (such 55,659 shares of common stock, the "Episodic Migraine Contingent Consideration Shares"); provided that in the event the satisfaction of the conditions for the issuance of the Episodic Migraine Contingent Consideration Shares occurs prior to the satisfaction of the conditions for the issuance of the Chronic Migraine Contingent Consideration Shares, then the number of Episodic Migraine Contingent Consideration Shares shall be increased to 152,998 shares of common stock; and
- 97,339 shares of common stock, in the aggregate, if, on or before June 30, 2028 (as it may be extended, the "Chronic Migraine Outside Date", and together with the Migraine Phase 3 Outside Date, the CD BLA Outside Date and the Episodic Migraine Outside Date, the "Outside Dates"), the Company shall have received from the FDA acceptance for review of the BLA submitted by AEON for the treatment of chronic migraine (such 97,339 shares of common stock, the "Chronic Migraine Contingent Consideration Shares"); provided that in the event that the number of Episodic Migraine Contingent Consideration Shares is increased to 152,998, then the number of Chronic Migraine Contingent Consideration Shares shall be decreased to zero and no Contingent Consideration Shares will be issued in connection with the satisfaction of the conditions to the issuance of the Chronic Migraine Contingent Consideration Shares.
- In the event that the Company licenses any of its products (except in connection with migraine or cervical dystonia indications) to a third-party licensor for distribution in the U.S. market (a "Qualifying License") prior to the satisfaction of (x) the conditions for the issuance of the Episodic Migraine Contingent Consideration Shares and (y) the conditions for the issuance of the Chronic Migraine Contingent Consideration Shares, then upon the entry of AEON into such Qualifying License, 27,992 shares of common stock shall become due and payable to Participating Stockholders and the number of Episodic Migraine Contingent Consideration Shares and (A) the number of Episodic Migraine Contingent Consideration Shares shall be reduced by 13,996 or by 27,992 and (B) the number of Chronic Migraine Contingent Consideration Shares shall be reduced by 13,996, but not below zero.

The Company accounts for the Contingent Consideration as either equity-classified or liability-classified instruments based on an assessment of the Contingent Consideration Shares specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). Based on the appropriate guidance, the Company determined that the Contingent Consideration would be classified as a liability on the Successor's consolidated balance sheets and remeasured at each reporting period with changes to fair value recorded to the Successor's consolidated statements of operations and comprehensive income (loss), while the founder shares were recorded to equity. As of December 31, 2024 and 2023 (Successor), the contingent consideration liability was \$3.5 million and \$104.4 million, respectively. The Company utilized the Probability-Weighted Expected Return Method (PWERM) model to value the contingent consideration based on earnout milestones,

probability of forfeiture and success scenarios. The Company recognized \$100.8 million and \$52.8 million in income related to the change in fair value of contingent consideration for the year ended December 31, 2024 (Successor) and for the period from July 22, 2023 to December 31, 2023 (Successor) on the consolidated statements of operations and comprehensive income (loss).

## **Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the financial statements as well as the expenses incurred during the reporting period. Generally, we base our estimates on historical experience and on various other assumptions in accordance with United States GAAP that we believe to be reasonable under the circumstances. Actual results may differ materially from these estimates under different assumptions or conditions and such differences could be material to the financial position and results of operations. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Report, we believe the following accounting policies to be most critical for fully understanding and evaluating our financial condition and results of operations, as these policies relate to the more significant areas involving management's judgments and estimates.

## Acquired in-Process Research and Development

The Company records costs incurred in obtaining technology licenses to research and development expense as acquired inprocess research and development ("IPR&D") if the technology licensed has not reached technological feasibility and has no
alternative future use. The Company used a Multi-Period Excess Earnings Method under the Income Approach for the valuation of
IPR&D. The valuation is subject to inputs and assumptions that have variability, including, but not limited to, the discount rate used,
the total addressable market for each potential drug, market penetration assumptions, and the estimated timing of commercialization of
the drugs. Changes in these inputs and assumptions could have a significant impact on the fair value of the IPR&D. The IPR&D
recorded at the Closing was written off in the Successor's consolidated statement of operations and comprehensive income (loss) (see
Note 3 Forward Merger to the consolidated financial statements).

## Contingent Consideration (Successor)

The Company accounts for its contingent consideration as either equity-classified or liability-classified instruments based on an assessment of the Contingent Consideration Shares specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). Based on the appropriate guidance, the Company determined that the Contingent Consideration would be classified as a liability on the Successor's consolidated balance sheets and remeasured at each reporting period with changes to fair value recorded to the Successor's consolidated statements of operations and comprehensive income (loss). The Company utilized the Probability-Weighted Expected Return Method (PWERM) model to value the contingent consideration based on earnout milestones, probability of forfeiture and success scenarios. The valuation is subject to inputs and assumptions that have variability, including stock price and milestone probabilities. As stock price and/or probabilities of achieving the milestones increases or decreases, this may result in an increase or decrease, respectively, in the liability.

#### Forward Purchase Agreements (Successor)

Based on the applicable guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"), the Company has determined it is a freestanding financial instrument and the prepaid forward contract is a derivative instrument. The Company has recorded the prepaid forward contract as a derivative liability and measured it at fair value with the initial value of the derivative recorded as a loss "on the line" in the Successor's opening accumulated deficit. Subsequent changes in the fair value of the forward purchase agreements are recorded in the Successor's consolidated statements of operations and comprehensive income (loss). The Company utilized the Monte-Carlo valuation model to value the forward purchase agreements.

The valuation is subject to inputs and assumptions that have variability, including stock price, risk-free rate and volatility, and changes in these inputs may result in increases or decreases in the liabilities.

## Warrants (Successor)

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC 480 and ASC Topic 815, "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own shares of common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter until settlement. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the consolidated statements of operations and comprehensive income (loss). Prior to the public warrant redemptions, the Company utilized the publicly reported market price of the public warrants to value the warrant liability. After the redemption, the Company uses the Black-Scholes model to value the private warrants. The valuation is subject to inputs and assumptions that have variability, including market price of warrants, and changes in warrant price may result in an increase or decrease in the liability.

## **Share-based Compensation**

The Company accounts for the measurement and recognition of compensation expense for all share-based awards based on the estimated fair value of the awards at grant date. The Company measures the fair value of awards granted using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including the Company's share price, expected volatility of the Company's common stock, expected risk-free interest rate, and the option's expected life. The Company also evaluates the impact of modifications made to the original terms of equity awards when they occur. The fair value of equity awards that are expected to vest is amortized on a straight-line basis over the requisite service period. Stock-based compensation expense is recognized net of actual forfeitures when they occur, as an increase to additional paid-in capital in the consolidated balance sheets and in selling, general and administrative or research and development expenses in the consolidated statements of operations and comprehensive income (loss). All stock-based compensation costs are recorded in the consolidated statements of operations and comprehensive income (loss) based upon the underlying employee's role within the Company.

## Convertible Notes

We elected to account for our convertible notes, which meets the required criteria, at fair value at inception. We recorded the initial fair value of the convertible notes as a liability on the consolidated balance sheets. Subsequent changes in fair value are recorded as a component of other income (loss) in the consolidated statements of operations and comprehensive income (loss) or as a component of other comprehensive income (loss) for changes related to instrument-specific credit risk. As a result of electing the fair value option, direct costs and fees related to the liabilities are expensed as incurred. The fair value of the convertible notes was determined based on Level 3 inputs using a scenario-based analysis that estimated the fair value of the convertible notes based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various qualified financings, corporate transaction and dissolution scenarios. The significant unobservable input assumptions that can significantly change the fair value included (i) the discount rates, (ii) the timing of payments, and (iii) the probability of certain settlement scenarios.

## **JOBS Act; Smaller Reporting Company**

We are an emerging growth company, as defined in the Securities Act, as modified by the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory

vote on executive compensation and any golden parachute payments not previously approved. In particular, in this Report, we have provided only two years of audited financial statements and unaudited financial statements and have not included all of the executive compensation- related information that would be required if we were not an emerging growth company. Section 102(b)(2) of the JOBS Act allows us to delay adoption of the new or revised accounting standards until those standards apply to non-public business entities. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of Priveterra's initial public offering (December 31, 2026), (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company," as such term is defined in Rule 12b-2 of the Exchange Act, meaning that the market value of our common stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue is less than \$100 million during the most recently completed fiscal year. We will continue to be a smaller reporting company if either (i) the market value of our common stock held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies.

Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. Investors could find our common stock less attractive to the extent we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the trading price may be more volatile.

## **Recently Issued and Adopted Accounting Pronouncements**

We describe the recently issued accounting pronouncements that apply to us in Note 2 of the consolidated financial statements.

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information under this Item.

## Item 8. Financial Statements and Supplementary Data

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of AEON Biopharma, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of AEON Biopharma, Inc. and subsidiary (the Company) as of December 31, 2024 and 2023 (Successor), the related consolidated statements of operations and comprehensive income (loss), convertible preferred stock and stockholders' deficit, and cash flows for the year ended December 31, 2024 (Successor) and for the periods from January 1, 2023 through July 21, 2023 (Predecessor), and July 22, 2023 through December 31, 2023 (Successor), and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023 (Successor), and the results of its operations and its cash flows for the year ended December 31, 2024 (Successor) and for the periods from January 1, 2023 through July 21, 2023 (Predecessor), and July 22, 2023 through December 31, 2023 (Successor), in conformity with U.S. generally accepted accounting principles.

## Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has experienced recurring losses from operations and has a net capital deficiency and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### /s/ KPMG LLP

We have served as the Company's auditor since 2023.

San Diego, California March 24, 2025

## AEON BIOPHARMA, INC. CONSOLIDATED BALANCE SHEETS

(in thousands, except share data and par value amounts)

	De	cember 31, 2024	De	cember 31, 2023
ASSETS				
Current assets:				
Cash and cash equivalents	\$	13	\$	5,158
Prepaid expenses and other current assets		1,577		1,064
Total current assets		1,590		6,222
Property and equipment, net		235		332
Operating lease right-of-use asset		1,288		262
Other assets		29		29
Total assets	\$	3,142	\$	6,845
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$	5,910	\$	3,388
Accrued clinical trials expenses		3,571		5,128
Accrued compensation		1,068		943
Other accrued expenses		3,600		3,590
Total current liabilities		14,149		13,049
Convertible notes at fair value, including related party amount of \$11,689 and \$0, at				
December 31, 2024 and December 31, 2023, respectively		11,689		_
Operating lease liability		1,145		_
Warrant liability		1,187		1,447
Contingent consideration liability		3,541		104,350
Embedded forward purchase agreements and derivative liabilities				41,043
Total liabilities		31,711		159,889
Commitments and contingencies				
Stockholders' Deficit:				
Class A common stock, \$0.0001 par value; 500,000,000 shares authorized at				
December 31, 2024 and December 31, 2023, and 555,511 and 516,404 shares issued and				
outstanding at December 31, 2024 and December 31, 2023, respectively		4		4
Additional paid-in capital		403,024		381,264
Subscription receivables.		(421.505)		(60,710)
Accumulated deficit		(431,597)		(473,602)
Total stockholders' deficit	Φ.	(28,569)	Φ.	(153,044)
Total liabilities and stockholders' deficit	\$	3,142	\$	6,845

See accompanying notes to the consolidated financial statements

# AEON BIOPHARMA, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (in thousands, except share and per share data)

		Year Ended December 31,	
	2024	2023	2023
	Successor	Successor July 22 to December 31	Predecessor January 1 to July 21
Operating expenses:			
Selling, general and administrative	\$ 13,643	\$ 9,949	\$ 9,841
Research and development	14,181	13,243	19,803
Acquired in-process research and development	_	348,000	_
Change in fair value of contingent consideration	(100,809)	(52,750)	
Total operating costs and expenses	(72,985)	318,442	29,644
Income (loss) from operations	72,985	(318,442)	(29,644)
Other income (loss):			
Change in fair value of convertible notes	3,311	_	(19,359)
Change in fair value of warrants	(14,719)	2,318	_
derivative liabilities, net	(19,667)	(8,366)	(11,789)
Other income, net	95	536	114
Total other loss, net	(30,980)	(5,512)	(31,034)
Income (loss) before taxes	42,005	(323,954)	(60,678)
Income taxes	_		
Net income (loss)	\$ 42,005	\$ (323,954)	\$ (60,678)
Basic net income (loss) per share	\$ 77.74	\$ (627.33)	\$ (0.44)
Diluted net income (loss) per share	\$ 72.93	\$ (627.33)	\$ (0.44)
Weighted average shares of common stock outstanding used to			
compute basic net income (loss) per share	540,360	516,404	138,848,177
Weighted average shares of common stock outstanding used to			
compute diluted net income (loss) per share.	575,945	516,404	138,848,177

See accompanying notes to the consolidated financial statements

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (in thousands, except share data) **AEON BIOPHARMA, INC.** 

Total

Non-

Additional

Preferred Stock Convertible

		ımı			Additional					-1101	Iotai
	Preferred Stock	d Stock	Common Stock	Stock	Paid-in	Subscription	Subscription Accumulated	Treasury Stock		controlling	Stockholders,
	Shares	Amount	Shares	Amount	Capital	Receivables	Deficit	Shares A	Amount	Interest	Deficit
Balance as of January 1, 2024 (Successor)		-	516,404	8	\$ 381,264	\$ (60,710)	\$ (473,602)	-	\$  -		\$ (153,044)
Net income							42,005				42,005
Termination of Forward Purchase Agreements						60,710					60,710
Issuance of shares and reclassification of		١	27.310	١	14 979		l	ı	ı	١	14 979
Issuance of shares related to at-the-market					1						,
offering, net			2,241		147						147
Issuance of common stock			5,556		384		1	1			384
Stock-based compensation expense			4,000		6,250						6,250
Balance as of December 31, 2024 (Successor)		-	555,511	\$	\$ 403,024	-	\$ (431,597)	-	8	=	(28,569)
Balance as of July 22, 2023 (Successor)		- -	516,404	8	\$ 377,498	\$ (60,710) \$	\$ (149,648)		<b>%</b>		\$ 167,144
Net loss							(323,954)				(323,954)
Stock-based compensation expense					3,766						3,766
Balance as of December 31, 2023 (Successor)		- \$	516,404	8	\$ 381,264	\$ (60,710)	\$ (473,602)	-	\$		\$ (153,044)
Balance as of January 1, 2023 (Predecessor)	21,257,708	\$ 137,949	138,848,177	\$ 14	\$ 187,348	~	\$ (474,839)	(22,821) \$ (23) \$ 17,087	(23) \$	17,087	\$ (270,413)
Net loss							(60,678)			3	(60,678)
Stock-based compensation expense										3,235	3,235

See accompanying notes to the consolidated financial statements

3,235 17,036 (310,820)

(22,821)

17,036 \$ 204,384

138,848,177

\$ 137,949

21,257,708

Debt extinguishment due to warrant modification. Balance as of July 21, 2023 (Predecessor)......

## AEON BIOPHARMA, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands, except per share data)

		Year Ended December 31,	
	2024	20	23
	Successor	Successor July 22 to December 31	Predecessor January 1 to July 21
Cash flows from operating activities:			
Net income (loss)	\$ 42,005	\$ (323,954)	\$ (60,678)
Adjustments to reconcile net income (loss) to net cash used in operating			
activities:			
Depreciation	97	45	54
Stock-based compensation expense	6,250	3,766	3,235
Non-cash issuance of common stock	384		_
Write-off of acquired in-process research and development		348,000	_
Change in fair value of convertible notes	(3,311)	_	19,359
Change in fair value of warrants	14,719	(2,318)	_
Change in fair value of embedded forward purchase agreements and			
derivative liabilities	19,667	8,366	11,789
Change in fair value of contingent consideration	(100,809)	(52,750)	_
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(513)	(693)	36
Accounts payable	2,522	(4,342)	(248)
Accrued expenses and other liabilities	(1,423)	(2,204)	4,736
Other assets and liabilities	120	4	(28)
Net cash used in operating activities	(20,292)	(26,080)	(21,745)
Net cash used in investing activities			
Cash flows from financing activities:			
Proceeds from issuance of convertible notes	15,000	_	14,000
Proceeds from issuance of at-the-market shares	147	_	_
Net cash provided by financing activities	15,147		14,000
Net decrease in cash	(5,145)	(26,080)	(7,745)
Cash and cash equivalents at beginning of period	5,158	31,238	9,746
Cash and cash equivalents at end of period	\$ 13	\$ 5,158	\$ 2,001

See accompanying notes to the consolidated financial statements

## AEON BIOPHARMA, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Note 1. Organization

## Description of Business

AEON Biopharma, Inc. (formerly known as Priveterra Acquisition Corp.; "AEON" or the "Company") is a biopharmaceutical company focused on developing its proprietary botulinum toxin complex, ABP-450 (prabotulinumtoxinA) injection ("ABP-450"), for debilitating medical conditions. The Company is headquartered in Irvine, California.

On July 21, 2023 (the "Closing Date"), the Company completed the acquisition of AEON Biopharma Sub, Inc. (formerly known as AEON Biopharma, Inc.) ("Old AEON") pursuant to the definitive agreement dated December 12, 2022 (the "Business Combination Agreement"), as amended April 27, 2023, by and among Priveterra Acquisition Corp. ("Priveterra"), Priveterra's wholly-owned subsidiary, Priveterra Merger Sub, Inc., and Old AEON. Old AEON was incorporated in Delaware in February 2012 under the name Alphaeon Corporation as a wholly-owned subsidiary of Strathspey Crown Holdings Group, LLC ("SCH"). On December 18, 2019, the Company changed its name to "AEON Biopharma, Inc." On the Closing Date, Old AEON merged with Priveterra Merger Sub, Inc., with Old AEON surviving the merger as a wholly-owned subsidiary of the Company. Also on the Closing Date, the Company changed its name from "Priveterra Acquisition Corp." to "AEON Biopharma, Inc." and is referred to herein as "AEON," or the "Company." Unless the context otherwise requires, references to "Priveterra" herein refer to the Company prior to the Closing Date.

Under the Business Combination Agreement, the Company agreed to acquire all outstanding equity interests of Old AEON for approximately 229,167 shares of Class A common stock, par value \$0.0001 per share ("common stock"), which Old AEON's stockholders received in the form of shares of common stock of the Company (the consummation of the Merger and the other transactions contemplated by the Business Combination Agreement, collectively, the "Merger"). In addition, following the closing of the Merger (the "Closing"), certain AEON stockholders will be issued up to 222,653 additional shares of common stock to the extent certain milestones are achieved.

Prior to the Closing, Priveterra shares were listed on Nasdaq as "PMGM." The post-Merger Company common stock and warrants commenced trading on the NYSE American under the symbols "AEON" and "AEON WS," respectively, on July 24, 2023. See Note 3 Forward Merger for additional details. The outstanding public warrants were fully redeemed in April 2024, and as such, there are no public warrants outstanding as of December 31, 2024. Refer to Note 6 for additional information.

## Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern. The Company has experienced recurring losses from operations and has a net capital deficiency and negative cash flows from operations since its inception. As of December 31, 2024, the Company reported cash of \$13 thousand and an accumulated deficit of \$431.6 million. The Company expects to incur losses and use cash in its operations for the foreseeable future.

On May 3, 2024, the Company announced preliminary top-line results from its planned interim analysis of the Phase 2 trial with ABP-450 in the preventative treatment of chronic migraine, which did not meet the primary or secondary endpoints. The Company originally intended to pursue submission of an Original BLA seeking one or more potential therapeutic indications for ABP-450. However, in May 2024, the Company announced the discontinuation of its Phase 2 clinical trials for episodic and chronic migraine in order to implement certain cash preservation measures. On July 9, 2024, the Company announced a strategic reprioritization to pursue a Section 351(k) biosimilar regulatory pathway for ABP-450, using AbbVie Inc.'s product Botox as a proposed reference product. The Company held an initial meeting with the FDA in the third quarter of 2024 during which it aligned with the FDA on next steps to develop a Botox biosimilar. The Company commenced analytical studies in the fourth quarter of 2024 to prepare for a potential Biosimilar Biological Product Development ("BPD") Type 2a meeting with the FDA to review the results from the studies in the second half of 2025.

On August 14, 2024, the Company entered into an "at-the-market" sales agreement with Leerink Partners LLC ("Leerink Partners") relating to an at-the-market offering program (the "ATM"), pursuant to which the Company may offer and sell, from time to time at its sole discretion, shares of common stock, registered pursuant to a shelf registration statement on Form S-3 that the

Securities and Exchange Commission (the "SEC") declared effective on August 21, 2024, having aggregate gross proceeds of up to \$50.0 million through Leerink Partners as sales agent. As of December 31, 2024, the Company issued 2,241 shares under the ATM for net proceeds of \$0.2 million and approximately \$49.8 million of common stock remained available to be sold under the ATM. See Note 8 Common Stock for additional information.

The commencement of studies, preparation for the potential BPD meeting and any further development of ABP-450 would require additional funding in the form of equity financings or debt. There can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of such financing will be commercially acceptable. Furthermore, the use of equity as a source of financing would dilute existing shareholders. The Company is actively attempting to secure additional capital to fund its operations. However, there can be no assurance that the Company will be able to raise additional capital on commercially reasonable terms or at all. As a result of these conditions, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern and to meet its obligations as they become due within one year after the date that these consolidated financial statements are issued.

The preparation of these consolidated financial statements does not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of the Company's liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects of the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. If the Company is unable to obtain adequate capital, it could be forced to cease operations.

The Company's future operations are highly dependent on a combination of factors, including (1) the success of its research and development programs; (2) the timely and successful completion of any additional financing; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies; (4) the Company's ability to manage growth of the organization; (5) the Company's ability to protect its technology and products; and, ultimately (6) regulatory approval and successful commercialization and market acceptance of its product candidates.

## Note 2. Summary of Significant Accounting Policies

## **Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its controlled subsidiaries.

On July 21, 2023, AEON completed the Merger with Old AEON, with Old AEON surviving the merger as a wholly-owned subsidiary of the Company, the accounting acquirer. The transaction was accounted for as a forward merger asset acquisition.

Unless the context otherwise requires, the "Company," for periods prior to the Closing, refers to Old AEON, AEON Biopharma Sub, Inc. ("Predecessor"), and for the periods after the Closing, refers to AEON Biopharma, Inc., including AEON Biopharma Sub, Inc. ("Successor"). As a result of the Merger, the results of operations, financial position and cash flows of the Predecessor and Successor are not directly comparable. AEON Biopharma Sub, Inc. was deemed to be the predecessor entity. Accordingly, the historical financial statements of AEON Biopharma Sub, Inc. became the historical financial statements of the combined Company, upon the consummation of the Merger. As a result, the financial statements included in this report reflect (i) the historical operating results of AEON Biopharma Sub, Inc. prior to the Merger and (ii) the combined results of the Company, including AEON Biopharma Sub, Inc., following the Closing. The accompanying financial statements include a Predecessor period, which includes the period through July 21, 2023 concurrent with the Merger, and a Successor period from July 22, 2023 through December 31, 2023. A black line between the Successor and Predecessor periods has been placed in the consolidated financial statements and in the tables to the notes to the consolidated financial statements to highlight the lack of comparability between these two periods.

## Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes. The Company's most significant estimates relate to the research and development accruals, valuation of common stock and related stock-

based compensation, and the fair values of contingent consideration, forward purchase agreements, in-process research and development, warrant liabilities, convertible notes, among others. Although the Company bases estimates on historical experience, knowledge of current events and actions it may undertake in the future, and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments over the carrying values of assets and liabilities, this process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

## Segment Reporting

The Company determined that it operates and manages its business as one operating segment, focused on the research and development of ABP-450. The Company's chief operating decision maker ("CODM") is the Company's Chief Executive Officer, who reviews its consolidated operating results for the purpose of assessing liquidity needs, allocating resources and evaluating financial performance. Asset information, including monitoring of its cash and cash equivalents, provided to the CODM is consistent with those reported on the consolidated balance sheets. The key measure of the Company's single segment profit and loss that the CODM uses to allocate resources and assess performance is the Company's operating income (loss) as reported on the consolidated statement of operations and comprehensive income (loss).

The table below shows a reconciliation of the Company's net income (loss), including the significant expense categories regularly provided to and reviewed by the CODM, as computed under US GAAP to the Company's total consolidated net income (loss) as reported in the consolidated statement of operations:

		Year Ended December 31,	
	2024	2023	2023
	Successor	Successor July 22 to December 31	Predecessor January 1 to July 21
Segment operating expenses:			
Compensation and benefits	\$ 9,153	\$ 5,377	\$ 5,548
Professional and legal fees	6,233	5,499	5,641
Office and travel	1,533	886	470
Research and development	10,905	11,430	17,985
Total selling, general and administrative, and research and development	27,824	23,192	29,644
Acquired in-process research and development	_	348,000	_
Change in fair value of contingent consideration	(100,809)	(52,750)	
Total operating costs and expenses	(72,985)	318,442	29,644
Income (loss) from operations	72,985	(318,442)	(29,644)
Other segment items:			
Change in fair value of convertible notes	3,311	_	(19,359)
Change in fair value of warrants	(14,719)	2,318	
Loss on embedded forward purchase agreements and derivative liabilities, net	(19,667)	(8,366)	(11,789)
Other income, net	95	536	114
Total other segment items, net	(30,980)	(5,512)	(31,034)
Income (loss) before taxes	42,005	(323,954)	(60,678)
Income taxes			
Segment net income (loss)	\$ 42,005	\$ (323,954)	\$ (60,678)

## Risk and Uncertainties

The Company is subject to risks common to early-stage companies in the pharmaceutical industry including, but not limited to, dependency on the clinical and commercial success of its current and any future product candidates, ability to obtain regulatory

approval of its current and any future product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and patients and significant competition.

The Company relies on Daewoong Pharmaceutical Co., Ltd. ("Daewoong"), a South Korean pharmaceutical manufacturer, as an exclusive and sole supplier to manufacture the Company's source material for product candidates. Any termination or loss of significant rights, including exclusivity, under the Company's license and supply agreement with Daewoong (the "Daewoong Agreement") would materially and adversely affect the Company's commercialization of its products. See Note 7 Commitments and Contingencies for a discussion of the Daewoong Agreement.

## Property and Equipment

Property and equipment are carried at cost less accumulated depreciation and amortization. The cost of property and equipment is depreciated over the estimated useful lives of the respective assets. The Company's furniture and fixtures are depreciated on a straight-line basis over a period of seven years. Equipment is depreciated over a useful life of five years. Leasehold improvements are amortized over the lesser of the estimated useful life of the asset or the related lease term. Property and equipment, net, as of December 31, 2024 and December 31, 2023 are as follows (in thousands):

	December 31,					
		2024		2023		
Furniture and fixtures	\$	199	\$	199		
Equipment		237		237		
Leasehold improvements		66		66		
Property and equipment		502		502		
Accumulated depreciation		(267)		(170)		
Property and equipment, net	\$	235	\$	332		

## Other Accrued Expenses

Other accrued expenses were as follows (in thousands):

	December 31,			
		2024		2023
Legal expenses	\$	2,455	\$	1,867
Excise tax liability		569		569
Operating lease liability - short term portion		121		278
Daewoong vial usage.		_		33
Remaining other accrued expenses		455		843
Total other accrued expenses	\$	3,600	\$	3,590

#### Convertible Notes

The Company elected to account for its convertible promissory notes at fair value at inception and at each subsequent reporting date. Subsequent changes in fair value are recorded as a component of non-operating income (loss) in the consolidated statements of operations or as a component of other comprehensive income (loss) for changes related to instrument-specific credit risk. As a result of electing the fair value option, direct costs and fees related to the convertible promissory notes are expensed as incurred. The Predecessor convertible promissory notes were converted into shares of the Company's common stock at the Closing.

## Contingent Consideration (Successor)

The Company accounts for its contingent consideration as either equity-classified or liability-classified instruments based on an assessment of the Contingent Consideration specific terms (as further defined in Note 6) and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). Based on the appropriate guidance, the Company determined that the Contingent Consideration would be classified as a

liability on the Successor's consolidated balance sheets and remeasured at each reporting period with changes to fair value recorded to the Successor's consolidated statements of operations and comprehensive income (loss).

## Forward Purchase Agreements (Successor)

Based on the applicable guidance in ASC 480, ASC 815, Equity ("ASC 505") and Staff Accounting Bulletin Topic 4.E, Receivables from Sale of Stock ("SAB 4E"), the Company had determined that each of its forward purchase agreements entered in connection with the Merger was a freestanding hybrid financial instrument comprising a subscription receivable and embedded features, which were bifurcated and accounted for separately as derivative instruments. The Company recorded the derivatives as liabilities and measured them at fair value each reporting period. For more information, see Note 3 Forward Merger. Subsequent changes in the bifurcated derivatives were recorded in the Successor's consolidated statements of operations and comprehensive income (loss). The forward purchase agreements were terminated in March 2024, and the loss related to the termination was recorded to the consolidated statement of operations and comprehensive income (loss).

## Warrants (Successor)

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments and meet all of the requirements for equity classification, including whether the warrants are indexed to the Company's own shares of common stock, among other conditions for equity classification. This assessment is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter until settlement. Changes in the estimated fair value of the warrants are recognized in the Successor's consolidated statements of operations and comprehensive income (loss).

## Convertible Preferred Stock (Predecessor)

The Company recorded its Predecessor convertible preferred stock at their respective issuance price, less issuance costs on the dates of issuance. As part of the Merger, each share of Old AEON common stock issued with respect to the Old AEON convertible preferred stock was converted into approximately 0.0323 shares of common stock and the right to receive a pro-rata portion of the contingent consideration.

## Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Fair value measurements are based on a three-tiered valuation hierarchy, which is classified and disclosed by the Company in one of the three categories as follows:

- Level 1 Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2 Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities in active markets; quoted prices in markets that are not active; or other inputs that are observable, either directly or indirectly, or can be corroborated by observable market data for substantially the full term of the asset or liability; and
- Level 3 Prices or valuation techniques that require unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

#### Leases

The Company determines whether a contract is, or contains, a lease at inception. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term using the Company's incremental borrowing rate applicable to the underlying asset unless the implicit rate is readily determinable. The Company determines the lease term as the noncancellable period of the lease, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the balance sheets.

## Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of costs associated with clinical studies including clinical trial design, clinical site reimbursement, data management, travel expenses and the cost of products used for clinical trials and internal and external costs associated with the Company's regulatory compliance and quality assurance functions, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings, and overhead costs. Additionally, research and development expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses and an allocation of facility overhead expenses. Costs incurred in obtaining technology licenses are charged to acquired in-process research and development ("IPR&D") if the technology licensed has not reached technological feasibility and has no alternative future use. The acquired IPR&D at the Closing was written off to the Successor's consolidated income statement for the period ended December 31, 2023.

The Company accrues the expenses for its clinical trial activities performed by third parties, including clinical research organizations and other service providers, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company determines these estimates through discussion with internal personnel and outside service providers as to progress or stage of completion of trials or services pursuant to contracts with clinical research organizations and other service providers and the agreed-upon fee to be paid for such services. Payments made to outside service providers in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. There have been no material adjustments to the Company's estimates for clinical trial expenses through December 31, 2024 (Successor) and December 31, 2023 (Successor).

## Stock-Based Compensation

The Company recognizes compensation expense for all share-based awards. The Company accounts for stock-based compensation as measured at grant date, based on the fair value of the award. The Company measures the fair value of awards granted using the Black-Scholes option pricing model, which requires the input of subjective assumptions, including the estimated fair value of common stock, the expected volatility of the Company's common stock, expected risk-free interest rate, and the option's expected life. The Company also evaluates the impact of modifications made to the original terms of equity awards when they occur.

The fair value of equity awards that are expected to vest is amortized on a straight-line basis over the requisite service period. Stock-based compensation expense is recognized net of actual forfeitures when they occur, as an increase to additional paid-in capital in the consolidated balance sheets and in selling, general and administrative or research and development expenses in the consolidated statements of operations and comprehensive income (loss). All stock-based compensation costs are recorded in the consolidated statements of operations and comprehensive income (loss) based upon the underlying employee's role within the Company.

## Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such

items are expected to reverse. A valuation allowance is provided against deferred tax assets unless it is more likely than not that they will be realized.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) it determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more-likely-than-not recognition threshold, it recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the accompanying consolidated statements of operations and comprehensive income (loss). Any accrued interest and penalties related to uncertain tax positions will be reflected as a liability in the consolidated balance sheets.

## Net Income (Loss) Per Share Attributable to Common Stockholders

Prior to the Merger, the Predecessor calculated basic and diluted net loss per share to common stockholders in conformity with the two-class method required for companies with participating securities. The Company considered all series of convertible preferred stock to be participating securities as they participate in any dividends declared by the Company. Under the two-class method, undistributed earnings allocated to these participating stockholders were subtracted from net income in determining net income attributable to common stockholders. Net loss attributable to common stockholders was not allocated to convertible preferred stock as the holders of convertible preferred stock did not have a contractual obligation to share in losses.

Subsequent to the Merger, the Company only has one class of shares. Basic net income (loss) per share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive shares of common stock. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average shares of common stock and potentially dilutive securities outstanding during the period using the treasury stock and if-converted methods, unless their inclusion would have been anti-dilutive. For purposes of the diluted net loss per share calculation, convertible preferred stock, warrants, convertible notes and common stock options were considered as potentially dilutive securities.

For the year ended December 31, 2024 (Successor), dilutive stock options of 24,245 and restricted stock units of 11,339 were included in the calculation of diluted net income per share. Since the Company was in a loss position for the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), basic net loss per share is the same as diluted net loss per share as the inclusion of all potentially dilutive shares of common stock was anti-dilutive.

Basic and diluted net income per share for the year ended December 31, 2024 was calculated as follows (in thousands, except share and per share amounts):

Year ended December 31, 2024 (Successor)	
Net income	\$ 42,005
Weighted average shares of common stock outstanding, basic	540,360
Net income per share, basic	\$ 77.74
Weighted average shares of common stock outstanding, diluted	575,945
Net income per share, diluted	

Basic and diluted net loss per share for the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor) were calculated as follows (in thousands, except share and per share amounts):

Period from January 1, 2023 to July 21, 2023 (Predecessor)		
Net loss.	\$	(60,678)
Weighted average shares of common stock outstanding, basic and diluted	1	38,848,177
Net loss per share, basic and diluted	\$	(0.44)
	<del></del>	
Period from July 22, 2023 to December 31, 2023 (Successor)		
Net loss.	\$	(323,954)
Weighted average shares of common stock outstanding, basic and diluted		516,404
Net loss per share, basic and diluted.	\$	(627.33)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an anti-dilutive impact:

	December 31,					
	2024	20	23			
	Successor	Successor July 22 to December 31	Predecessor January 1 to July 21			
Warrants	55,403	201,112	14,479,999			
Common stock options and restricted stock units	88,999	67,927	4,888,537			
Convertible notes	399,128					
	543,530	269,039	19,368,536			

# **Contingencies**

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. The Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the litigation, including an estimable range, if possible.

### Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures. This update requires public entities to disclose information about their reportable segments' significant expenses that are regularly provided to the CODM and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280, on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 31, 2023, and for interim periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard during its fiscal year ended December 31, 2024. For the purpose of the adoption of ASU 2023-07, the Company performed an evaluation of financial information regularly reviewed by the Company's CODM for purposes of assessing liquidity needs, allocating resources and evaluating performance. See Note 2 Summary of Significant Accounting Policies - Segment Reporting for more information.

# Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740)*, *Improvements to Income Tax Disclosures*. This update requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income

taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which is intended to improve financial reporting by requiring disaggregated disclosure of certain costs and expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted, and may be applied on either a prospective or retrospective basis. The Company is currently evaluating the impact of this guidance on its consolidated financial statements.

Other recent accounting pronouncements issued by the FASB, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission (the "SEC") did not, or are not believed by management to, have a material impact on the Company's financial position, results of operations or cash flows.

# Note 3. Forward Merger

On December 12, 2022, Old AEON and Priveterra entered into a Business Combination Agreement. On July 21, 2023, the parties consummated the Merger. In connection with the Closing, Priveterra changed its name from Priveterra Acquisition Corp. to AEON Biopharma, Inc.

At the effective time of the Merger (the "Effective Time"), each outstanding share of Old AEON common stock (on an asconverted basis after taking into effect the conversion of the outstanding warrants of Old AEON exercisable for shares of Old AEON preferred stock, the conversion of the shares of Old AEON preferred stock into Old AEON common stock in accordance with the governing documents of Old AEON as of the Effective Time, the conversion of the outstanding convertible notes of Old AEON into Old AEON common stock in accordance with the terms of such convertible notes and after giving effect to the issuance of Old AEON common stock in connection with the merger of ABP Sub, Inc. with and into Old AEON) issued and outstanding immediately prior to the Effective Time converted into the right to receive approximately 0.0323 shares of the Company's common stock and the right to receive a pro-rata portion of the contingent consideration. In addition, each share of Priveterra Class B common stock ("Founder Shares"), par value \$0.0001 per share, issued and outstanding immediately prior to the Effective Time converted into one share of common stock totaling 95,842 common shares (of which 47,921 Founder Shares are subject to certain vesting and forfeiture conditions).

In connection with the Merger, on January 6, 2023, Priveterra and Old AEON entered into separate subscription agreements for convertible notes with each of Alphaeon 1 LLC ("A1") and Daewoong Pharmaceuticals Co., Ltd. ("Daewoong") (collectively, the "Original Committed Financing Agreements"), pursuant to which A1 and Daewoong agreed to purchase, and Priveterra and Old AEON agreed to sell to each of them, up to \$15 million and \$5 million, respectively, aggregate of principal of interim convertible notes or equity. Further, on June 8, 2023, Old AEON and Priveterra entered into a committed financing agreement with A1 (the "Additional Committed Financing Agreement"), pursuant to which A1 agreed to purchase, and Priveterra and Old AEON agreed to sell to A1, up to an additional \$20 million aggregate principal of interim convertible notes or equity. Pursuant to such agreement, Old AEON issued \$14 million of interim convertible notes to A1 in the first and second quarters of 2023. The notes were subsequently measured at fair value under a fair value option election, with changes in fair value reported in earnings of the Predecessor (Old AEON). Conversion of the notes was contingent and automatically convertible on the Merger, and 30,920 shares of Priveterra Class A common stock were issued on the Closing Date in settlement of their conversion. The proceeds from the interim convertible notes were used to fund Old AEON's operations through the consummation of the Merger. Additionally, approximately \$25 million was received on the Closing Date in exchange for an aggregate of 49,604 shares of Priveterra Class A common stock at \$504.00 per share that were issued under the Original Committed Financing Agreements and Additional Committed Financing Agreements, and was reflected "on the line" in the Successor's opening accumulated deficit.

On April 27, 2023, Priveterra and AEON amended the Business Combination Agreement. Concurrently with the amendment to the Business Combination Agreement, Priveterra amended the Sponsor Support Agreement to include restriction and forfeiture provisions related to the Founder Shares. See Note 6 Fair Value Measurements for additional information. The fair value of the contingent consideration at the Closing was valued to be \$125.7 million, and is included in the purchase price. Additionally, the Successor assumed the Predecessor's 2019 Incentive Award Plan, and as such, the fair value of the replacement awards of \$13.3 million were included in purchase consideration, \$11.5 million related to stock options and \$1.8 million related to restricted stock units. See Note 10 Share-Based Compensation for additional information.

## Asset Acquisition Method of Accounting

The Merger was accounted for using the asset acquisition method in accordance with U.S. GAAP. Under this method of accounting, Priveterra was considered to be the accounting acquirer based on the terms of the Merger. Upon consummation of the Merger, the cash on hand resulted in the equity at risk being considered insufficient for Old AEON to finance its activities without additional subordinated financial support. Therefore, Old AEON was considered a Variable Interest Entity ("VIE") and the primary beneficiary of Old AEON was treated as the accounting acquirer. Priveterra held a variable interest in Old AEON and owned 100% of Old AEON's equity. Priveterra was considered the primary beneficiary as it has the decision-making rights that gives it the power to direct the most significant activities. Also, Priveterra retained the obligation to absorb the losses and/or receive the benefits of Old AEON that could have potentially been significant to Old AEON. The Merger was accounted for as an asset acquisition as substantially all of the fair value was concentrated in IPR&D, an intangible asset. Old AEON's assets (except for cash) and liabilities were measured at fair value as of the transaction date. Consistent with authoritative guidance on the consolidation of a VIE that is not considered a business, differences in the total purchase price and fair value of assets and liabilities are recorded as a gain or loss to the consolidated statement of operations. The loss on the consolidation of the VIE is reflected "on the line" in the Successor's opening accumulated deficit.

Costs incurred in obtaining technology licenses are charged to research and development expense as IPR&D if the technology licensed has not reached technological feasibility and has no alternative future use. The IPR&D recorded at the Closing of \$348.0 million was written off in the Successor's consolidated statement of operations and comprehensive income (loss). To estimate the value of the acquired IPR&D, the Company used a Multi-Period Excess Earnings Method under the Income Approach. The determination of the fair value requires management to make significant estimates including, but not limited to, the discount rate used, the total addressable market for each potential drug, market penetration assumptions, and the estimated timing of commercialization of the drugs. Changes in these assumptions could have a significant impact on the fair value of the IPR&D. The significant assumptions used in determining IPR&D was the discount rate of 25%, implied internal rate of return of 24.8% and long-term growth rate of 4%.

The following is a summary of the purchase price calculation (in thousands except share and per share data).

	Number of shares issued as consideration in the Merger		229,167
	Shares issued for interim convertible notes related to Committed Financing		30,920
	Total number of shares of common stock of the combined company		260,087
	Multiplied by the Priveterra share price, as of the Closing	\$	780.48
	Total	\$	202,992
	Fair value of contingent consideration		125,699
	Replacement of share-based payment awards		13,331
	Assumed liabilities.		125
	Total purchase price	\$	342,147
The	allocation of the purchase price was as follows (in thousands).		
	Cash and cash equivalents	\$	2,001
	Net working capital (excluding cash and cash equivalents)	•	(16,182)
	Other assets and liabilities		775
	Acquired in-process research and development		348,000
	Net assets acquired		334,594
	Loss on consolidation of VIE		7,553
	Total purchase price.	\$	342,147

In connection with the Merger, the transactions that occurred concurrently with the closing date of the Merger were reflected "on the line". "On the line" describes those transactions triggered by the consummation of the Merger that are not recognized in the consolidated financial statements of the Predecessor nor the Successor as they are not directly attributable to either period but instead were contingent on the Merger. The opening cash balance in the Successor's consolidated statement of cash flow of \$31.2 million consists of cash from Priveterra of \$29.2 million and Old AEON \$2.0 million. The number of shares of common stock issued and amounts recorded on the line within stockholders' deficit are reflected below to arrive at the opening consolidated balance sheet of the Successor.

		Shares of common stock	st	mmon tock tount	bscription eceivable	APIC	Ac	cumulated Deficit
Priveterra closing equity as of July 21, 2023		7,739	\$	_	\$ _	\$ 5,937	\$	(12,897)
Shares issued as Consideration in the Merger	Note 1	229,167		2	_	192,189		
Merger Consideration - Shares issued for Interim								
Convertible Notes related to Committed Financing	Note 5	30,920		_	_	24,132		_
Stock-Compensation for Class B Founder Shares	Note 3	95,842		1	_	68,972		(68,972)
Forward Purchase Agreements	Note 6	87,154		1	(60,710)	66,714		(38,255)
Issuance of Make-Whole derivative	Note 6	_		_	_	_		(427)
Shares issued in New Money PIPE Subscription								
Agreements	Note 6	13,910		_	_	10,844		(6,433)
Shares issued for Committed Financing	Note 6	49,604		_	_	38,714		(13,714)
Contingent Founder Shares	Note 6	_		_	_	(31,401)		
Loss on Consolidation of VIE	Note 3	_		_	_			(7,553)
Other Miscellaneous		2,068				1,397		(1,397)
Total		516,404	\$	4	\$ (60,710)	\$ 377,498	\$	(149,648)

The Sponsor, in connection with Priveterra's IPO, purchased 95,842 shares of Class B common stock (the "Founder Shares") for \$25,000 (approximately \$0.288 per share). These shares had no value until Priveterra effected the Merger. Upon the Merger, the Founder Shares automatically converted to shares of common stock. This conversion was solely contingent upon the completion of the Merger, a performance condition, and did not include any future service requirements. As such, the grant date fair value of the 95,842 shares was expensed in the amount of \$69.0 million and is presented "on the line." Pursuant to the terms of the Sponsor Support Agreement, as amended, effective at the Closing, 50% of the Founder Shares (i.e., 47,921 Founder Shares) (the "Contingent Founder Shares") were unvested and subject to the restrictions and forfeiture provisions set forth in this Sponsor Support Agreement. As such, the fair value at Closing of the remaining 47,921 shares with vesting conditions in the amount of \$31.4 million was reclassified from additional paid-in capital to contingent consideration liability on the accompanying Successor's consolidated balance sheet.

# **Note 4.** Related Party Transactions (Predecessor)

# 2019 Debt Financings

In June 2019, the Predecessor entered into a senior unsecured note purchase agreement (the "Original 2019 Note Purchase Agreement"), with Dental Innovations, pursuant to which the Predecessor issued Dental Innovations a promissory note (the "Original 2019 Note") with a principal amount of \$5.0 million. Pursuant to the terms of the Original 2019 Note, the Predecessor was required to repay a total of \$8.75 million, representing all principal and interest owed, upon the earliest to occur of (i) June 19, 2022, (ii) Dental Innovations' demand for repayment following the Predecessor's completion of an initial public offering and (iii) the Predecessor's election to repay the Original 2019 Note in full.

Under the Original 2019 Note Purchase Agreement, Dental Innovations committed to purchase from the Predecessor an additional promissory note with a principal amount of \$5.0 million, subject to the Predecessor issuing and selling an additional promissory note with a principal amount of \$5.0 million to a lender not affiliated with Dental Innovations. Any such additional promissory notes were to have the same payment terms as the Original 2019 Notes.

In December 2019, the Predecessor entered into an amendment to the Original 2019 Note Purchase Agreement that provided for the exchange of the Original 2019 Note for a convertible promissory note with a principal amount of \$5.0 million. In addition, Dental Innovations was no longer committed to purchase from the Predecessor an additional promissory note with a principal amount of \$5.0 million subject to the Predecessor issuing and selling an additional promissory note with a principal amount of \$5.0 million to a lender not affiliated with Dental Innovations. In December 2019, the Predecessor issued and sold five additional convertible promissory notes, each with a principal amount of \$1.0 million, including one to SCH and one to a member of the Predecessor's board of directors (all such convertible promissory notes, the "2019 Convertible Notes").

The Predecessor's payment and performance under the 2019 Convertible Notes were guaranteed by ABP Sub Inc., the Predecessor's wholly owned subsidiary prior to the Merger. Pursuant to the terms of the 2019 Convertible Notes, the Predecessor was required to repay 175% of the principal amount to the holders on the third anniversary of the issuance of the 2019 Convertible Notes. In the event of an underwritten public offering of the Predecessor's common stock, the 2019 Convertible Notes would have automatically converted into a number of shares of the Predecessor's common stock equal to 175% of the principal amount of the 2019 Convertible Notes, divided by the per share price at which shares were offered to the public in such offering.

Due to certain embedded features within the 2019 Convertible Notes, the Predecessor elected to account for the 2019 Convertible Notes and all their embedded features at fair value at inception. Subsequent changes in fair value were recorded as a component of other income (loss) in the Predecessor's consolidated statements of operations and comprehensive income (loss) or as a component of other comprehensive income (loss) for changes to instrument-specific credit risk. As a result of electing the fair value option, direct costs and fees related to the 2019 Convertible Notes were expensed as incurred.

In January 2020, in connection with the distribution of the units of A1 to the Predecessor's stockholders, each of the holders of the Predecessor's 2019 Convertible Notes were granted contingent warrants by A1 to purchase shares of Evolus, Inc. ("Evolus") from A1. The contingent warrants were exercisable at the option of the holders only prior to the Predecessor's first underwritten public offering of common stock under the Securities Act of 1933, as amended (the "Securities Act"), or upon an event of default under the 2019 Convertible Notes. The 2019 Convertible Notes were concurrently amended to provide the noteholders the option, prior to the notes' conversion, to cancel a portion of the indebtedness represented by such noteholder's 2019 Convertible Note and receive a number of shares of Evolus from A1 having a market value equal to the value of such cancelled indebtedness, in lieu of automatic conversion of all of the noteholder's 2019 Convertible Note into shares of the Predecessor's common stock. The amount of cancelled indebtedness that could be so applied in exercise of the contingent warrant was capped as the ratio that the value of Evolus shares held by A1 bore to the combined value of (i) the Evolus shares held by A1 and (ii) the Predecessor immediately prior to consummation of the Predecessor's first underwritten public offering of common stock under the Securities Act.

In September 2020, in connection with the distribution of the units of Alphaeon Credit Holdco LLC ("AC HoldCo") and Zelegent HoldCo LLC ("Z HoldCo") to the Predecessor's stockholders, each of the holders of the Predecessor's 2019 Convertible Notes were granted contingent warrants by AC HoldCo and Z HoldCo to purchase shares of Alphaeon Credit, Inc. ("Alphaeon Credit") and Zelegent from AC HoldCo and Z HoldCo. The contingent warrants were exercisable at the option of the holders only prior to the Predecessor's first underwritten public offering of common stock under the Securities Act, or upon an event of default under the 2019 Convertible Notes. The 2019 Convertible Notes were concurrently amended to provide the noteholders the option, prior to the notes' conversion, to cancel a portion of the indebtedness represented by such noteholder's 2019 Convertible Note and receive a number of shares of Alphaeon Credit and/or Zelegent from AC HoldCo and Z HoldCo having a market value equal to the value of such cancelled indebtedness, in lieu of automatic conversion of all of the applicable noteholder's 2019 Convertible Note into shares of the Predecessor's common stock. The amount of cancelled indebtedness that can be so applied in exercise of the contingent warrant was capped as the ratio of aggregate indebtedness held by the convertible note holder as a proportion of the value of Alphaeon Credit or Zelegent to the value of the Predecessor.

Additionally, on July 22, 2022, the 2019 debt was amended. The Dental Innovations note's maturity date was extended from June 19, 2022 to December 29, 2023. The original note had a principal of \$5.0 million. Upon the original maturity date, the total due was 175% of principal, which equals \$8.7 million (which such amount included an additional amount of \$3.7 million). Interest was increased from 0.0% to 15.79% on the total payable of \$8.7 million from the original maturity date of June 19, 2022 to the new maturity date of December 29, 2023.

On July 22, 2022, the maturity dates for four of the \$1.0 million convertible promissory notes were extended from November 1, 2022, December 12, 2022, December 12, 2022 and December 18, 2022, respectively, to December 29, 2023. Each of the four notes had a principal of \$1.0 million. Upon the original maturity date, the total due on each of the four notes was 175% of principal, which equals \$1.7 million (which such amount included an additional amount of \$0.7 million). At the original maturity dates, the principal sum of \$1.0 million was paid back to each of the note holders. The remaining \$0.7 million was to be due at the extended maturity date of December 29, 2023. The interest rate was increased from 0.0% to 10.0% interest on the remaining \$0.7 million from the original maturity date to the new maturity date.

The 2019 SCH Note's maturity date was extended from December 18, 2022 to December 29, 2023. The original Note had a principal of \$1.0 million. Upon the original maturity date, the total due was 175% of principal, which equals \$1.7 million. The interest rate was increased from 0.0% to 15.79% on the total of \$1.7 million from the original maturity date to the new maturity date.

In April 2023, the contingent warrants were amended to include the merger between AEON and Old AEON as a qualifying listing under the warrant agreement, which stated that the holders of the contingent warrants would exercise the warrants, and that the holders would receive 85% of the shares the holders would have been entitled to receive via the previous warrant agreement. The contingent warrants were exercised into Evolus shares held by A1 and Alphaeon Credit at the same time the convertible notes were converted to shares of the Company's stock. The Company determined that the contingent warrants amendment modified the settlement provision in the 2019 Convertible Notes. The Company determined that the amendment should be accounted for as a debt extinguishment. Since the noteholders were both shareholders of Old AEON, Evolus and Alphaeon Credit, the debt extinguishment was accounted for as a capital transaction on the April 2023 modification date. As such, due to the warrant modification, the Predecessor recognized a \$17.0 million reduction to the underlying fair value of the convertible notes and a corresponding increase of \$17.0 million to additional paid in capital during the period from January 1, 2023 to July 21, 2023 (Predecessor), of which \$5.2 million was attributable to 2019 Debt Financing contingent warrants.

During the period from January 1, 2023 to July 21, 2023 (Predecessor), the Predecessor recognized \$1.6 million of expense related to the increase in the fair value of the 2019 Convertible Notes. As of December 31, 2022 (Predecessor), the principal amount outstanding under the 2019 Convertible Notes was \$6.0 million, with an estimated fair value of \$16.2 million. The 2019 Convertible Notes were converted into shares of the Successor's common stock at the Closing and were recorded "on the line" as part of the shares issued as consideration in the Merger (see Note 3 Forward Merger).

### SCH Convertible Note

The Predecessor issued a convertible promissory note to SCH (the "SCH Convertible Note"). Prior to the Merger, the Predecessor's payment and performance under the SCH Convertible Note were guaranteed by ABP Sub Inc. Pursuant to the terms of the SCH Convertible Note, the Predecessor was required to repay 175% of the principal amount to SCH on the third anniversary of its issuance. In the event of an underwritten public offering of the Predecessor's common stock, the SCH Convertible Note would have automatically converted into a number of shares of the Predecessor's common stock equal to 175% of the principal amount of the SCH Convertible Note, divided by the per share price at which shares were offered to the public in such offering.

Due to certain embedded features within the SCH Convertible Note, the Predecessor elected to account for the SCH Convertible Note and the embedded features at fair value at inception. Subsequent changes in fair value were recorded as a component of other income (loss) in the Predecessor's consolidated statements of operations and comprehensive income (loss) or as a component of other comprehensive income (loss) for changes to instrument-specific credit risk. As a result of electing the fair value option, any direct costs and fees related to the SCH Convertible Note were expensed as incurred.

Additionally, the 2020 Strathspey Crown note's maturity date was extended from January 2, 2023 to December 29, 2023. The original note had a principal of \$17.5 million. Upon the original maturity date, the total due was \$30.6 million. The interest rate was increased from 0.0% to 15.79% on the total of \$30.6 million from the original maturity date to the new maturity date.

During the period from January 1, 2023 to July 21, 2023 (Predecessor), the Predecessor recognized \$4.2 million of expense related to the increase in the fair value of the SCH Convertible Note. As of December 31, 2022, the principal amount outstanding under the SCH Convertible Note was \$17.5 million, with an estimated fair value of \$25.1 million.

In April 2023, the contingent warrants were amended to include the merger between AEON and Old AEON as a qualifying listing under the warrant agreement, which stated that the holders of the contingent warrants would exercise the warrants, and that the holders would receive 85% of the shares the holders would have been entitled to receive via the previous warrant agreement. The Company determined that the contingent warrants amendment modified the settlement provision in the 2019 Convertible Notes. The Company determined that the amendment should be accounted for as a debt extinguishment. Since Evolus and Alphaeon Credit are related parties of AEON, the debt extinguishment was accounted for as a capital transaction on the April 2023 modification date. As such, due to the warrant modification, the Predecessor recognized a \$17.0 million reduction to the underlying fair value of the convertible notes and a corresponding increase of \$17.0 million to additional paid in capital during the period from January 1, 2023 to July 21, 2023 (Predecessor), of which \$11.8 million was attributable to SCH contingent warrants.

The SCH Convertible Note was converted into shares of the Successor's common stock at the Closing and was recorded "on the line" as part of the shares issued as consideration in the Merger (see Note 3 Forward Merger).

#### A1 Convertible Notes

In December 2021, the Predecessor entered into an agreement with A1 (the "A1 Purchase Agreement"), pursuant to which the Predecessor could issue subordinated convertible promissory notes to A1 with an aggregate principal amount of up to \$25.0 million. On December 8 and 15, 2021, the Predecessor issued two convertible notes (collectively, the "2021 A1 Convertible Notes"), each with a principal amount of \$5.0 million, and totaling \$10.0 million, that matured on the third anniversary of their issuance. The A1 Convertible Notes were unsecured and subordinated to the Predecessor's other convertible notes.

The 2021 A1 Convertible Notes bore interest, compounded daily, at the lesser of 10% per annum or the maximum rate permissible by law. Interest was paid in-kind by adding the accrued amount thereof to the principal amount on a monthly basis on the last day of each calendar month for so long as any principal amount was outstanding (such paid in-kind interest, in the aggregate at any time, the "PIK Principal").

Immediately prior to an initial public offering, all of the then outstanding principal amount and accrued and unpaid interest under the 2021 A1 Convertible Notes was to automatically convert into shares of the Predecessor's common stock. The number of shares of common stock issuable upon conversion of the 2021 A1 Convertible Notes would have been equal to (i) the outstanding loan amount (including the PIK Interest) divided by (ii) the product of (a) the price per share of such common stock issued to the public in the initial public offering *multiplied by* (b) the applicable discount rate. The discount rate was to be determined for each note based on the number of days elapsed between the date the applicable note was executed and the date on which a conversion event was formally announced and was to be equal to (x) 10% if between zero and 90 days, (y) 15% if between 91 and 180 days, or (z) 20% if greater than 180 days.

Due to certain embedded features within the 2021 A1 Convertible Notes, the Predecessor elected to account for the 2021 A1 Convertible Notes and the embedded features at fair value at inception. Subsequent changes in fair value were recorded as a component of other income (loss) in the accompanying Predecessor's consolidated statements of operations and comprehensive income (loss) or as a component of other comprehensive income (loss) for changes to instrument-specific credit risk.

During the period from January 1, 2023 to July 21, 2023 (Predecessor), the Predecessor recognized \$3.0 million of expense related to the increase in the fair value of the 2021 A1 Convertible Notes. As of December 31, 2022, the principal amount outstanding under the 2021 A1 Convertible Notes was \$10 million, with an estimated fair value of \$8.7 million. The 2021 A1 Convertible Notes were converted into shares of the Successor's common stock at the Closing.

During the year ended December 31, 2022, the Predecessor issued five additional tranches of subordinated convertible promissory notes to A1 on February 18, 2022, March 9, 2022, April 14, 2022, June 3, 2022 and July 1, 2022 (collectively, the "2022 A1 Convertible Notes"), the first four with a principal amount of \$3.0 million each and the fifth issued July 1, 2022, for a principal amount of \$2.5 million and totaling \$14.5 million. The terms of the 2022 A1 Convertible Notes were similar to those of the 2021 A1 Convertible Notes. During the period from January 1, 2023 to July 21, 2023 (Predecessor), the Predecessor recognized \$4.2 million of expense related to the increase in the fair value of the 2022 A1 Convertible Notes. As of December 31, 2022, the principal balance was \$14.5 million, with an estimated fair value of \$12.2 million. The 2022 A1 Convertible Notes were converted into shares of the Successor's common stock at the Closing.

Additionally, on March 30, 2022, the Predecessor amended the 2021 A1 Convertible Notes and the convertible notes issued on February 18, 2022 and March 9, 2022 to remove the discount rate associated with the automatic conversion of any outstanding convertible notes into shares of common stock in connection with an initial public offering.

On March 6, 2023, the Predecessor entered into an agreement with A1, pursuant to which the Predecessor issued subordinated convertible promissory notes to A1 with an aggregate principal amount of \$6.0 million ("March 2023 A1 Convertible Notes") that matured on the earlier of (x) the date of the consummation of the Merger and (y) December 29, 2023. The March 2023 A1 Convertible Notes bore interest at 15.79%, based on simple interest daily, unless issued at least five days prior to maturity date. The March 2023 A1 Convertible Notes had similar terms to the 2021 A1 Convertible Notes and 2022 A1 Convertible Notes and were unsecured and subordinated to the Predecessor's other convertible notes. During the period from January 1, 2023 to July 21, 2023 (Predecessor), the Predecessor recognized \$10.1 million of expense related to the increase in the fair value of the March 2023 A1 Convertible Notes. The March 2023 A1 Convertible Notes were converted into shares of the Successor's common stock at the Closing and was recorded "on the line" as part of the shares issued as consideration in the Merger (see Note 3 Forward Merger).

## **Note 5.** Daewoong Convertible Notes

Daewoong Convertible Notes (Predecessor)

In August 2020, the Predecessor entered into a Convertible Promissory Note Purchase Agreement with Daewoong (the "Daewoong Purchase Agreement"), pursuant to which the Predecessor issued Daewoong two subordinated convertible promissory notes (collectively, the "2020 Daewoong Convertible Notes") with an aggregate principal amount of \$25.0 million. The 2020 Daewoong Convertible Notes had similar terms, of which one was issued on August 27, 2020 with a principal amount of \$10.0 million and the other was issued on September 18, 2020 with a principal amount of \$15.0 million. The 2020 Daewoong Convertible Notes were unsecured and subordinated to the Predecessor's 2019 Convertible Notes. The Predecessor's payment and performance under the 2020 Daewoong Convertible Notes was guaranteed by ABP Sub Inc., the Predecessor's wholly owned subsidiary prior to the Merger.

The 2020 Daewoong Convertible Notes bore interest daily at 3% per annum with semiannual compounding. Interest is paid inkind by adding the accrued amount thereof to the principal amount on a semi-annual basis on June 30th and December 31st of each calendar year for so long as any principal amount remained outstanding (such paid in-kind interest, in the aggregate at any time, the "PIK Principal"). The 2020 Daewoong Convertible Notes had a maturity date of September 18, 2025.

Pursuant to the 2020 Daewoong Convertible Notes' terms, Daewoong could have elected to convert all of the then outstanding principal amount and all accrued and unpaid interest into the Predecessor's common stock at any time following the date that was 12 months after September 18, 2020, provided, that such election must have been made at the same time with respect to all notes issued to Daewoong. The number of shares issuable upon any conversion would have been equal to (i) the outstanding principal amount (excluding PIK Principal) divided by \$25.0 million and (ii) multiplied by 9.99% of the aggregate of all of the shares of the Predecessor's common stock then outstanding, the Predecessor's common stock issuable upon conversion or exercise of all of the outstanding convertible or exercisable securities, all outstanding vested or unvested options or warrants to purchase the Predecessor's capital stock, but excluding all out-of-the-money options, and all shares of common stock issuable upon conversion of any convertible debt (whether or not such debt would have been convertible at such time).

Immediately prior to an initial public offering ("IPO"), all of the then outstanding principal amount and accrued and unpaid interest under the 2020 Daewoong Convertible Notes would have automatically converted into shares of the Predecessor's common stock. The number of shares of common stock issuable upon conversion of the 2020 Daewoong Convertible Notes was equal to (i) the outstanding principal amount (excluding PIK Principal) divided by \$25.0 million and (ii) multiplied by the greater of (A) 9.99% of the pre-IPO shares of the Predecessor, and (B) that number of shares having an aggregate value of \$20.0 million immediately prior to the IPO based upon a price per share of such common stock issued to the public in the IPO; provided, however, that in no event was Daewoong's ownership to exceed 15% of the pre-IPO shares of the Predecessor after taking into account conversion of the 2020 Daewoong Convertible Notes. In the event, and only in the event, that shares of the Predecessor were sold in the IPO whereby the premoney valuation of the Predecessor was \$200.0 million or greater, within five business days of the conversion of the 2020 Daewoong Convertible Notes, the Predecessor would have been required pay to Daewoong the PIK Principal plus all accrued and unpaid interest either in cash or by the issuance of additional shares of common stock at the price per share in the IPO, which payment method would have been be at the Predecessor's sole election.

In May 2021, the Daewoong Purchase Agreement was amended to provide for the issuance of an additional subordinated convertible promissory note by the Predecessor to Daewoong at an initial principal amount of \$5.0 million. The subordinated convertible promissory note was issued with terms similar to the two subordinated convertible promissory notes issued in 2020 and had a maturity date of May 12, 2026 (all such convertible promissory notes, the "Daewoong Convertible Notes").

Pursuant to the terms of the amended Daewoong Purchase Agreement, Daewoong could have elected to convert all of the then outstanding principal amount and all accrued and unpaid interest into the Predecessor's common stock at any time following the date that was 12 months after September 18, 2020, provided, that such election must have been made at the same time with respect to all notes issued to Daewoong. The number of shares of common stock issuable upon conversion would have been equal to (i) the outstanding principal amount (excluding PIK Principal) divided by \$30.0 million and (ii) multiplied by 11.99% of the aggregate of all of the shares of the Predecessor's common stock then outstanding, the Predecessor's common stock issuable upon conversion or exercise of all of the outstanding convertible or exercisable securities, all outstanding vested or unvested options or warrants to purchase the Predecessor's capital stock, but excluding all out-of-the-money options, and all shares of common stock issuable upon conversion of any convertible debt (whether or not such debt would have been convertible at such time).

In addition, immediately prior to an initial public offering, all of the then outstanding principal amount and accrued and unpaid interest under the convertible notes would have automatically converted into shares of the Predecessor's common stock. The number of shares of common stock issuable upon conversion of the convertible notes was equal to (i) the outstanding principal amount (excluding PIK Principal) divided by \$30.0 million and (ii) multiplied by the greater of (A) 11.99% of the pre-IPO shares of the Predecessor, and (B) that number of shares having an aggregate value of \$24.0 million immediately prior to the IPO based upon a price per share of such common stock issued to the public in the IPO; provided, however, that in no event was Daewoong's ownership to exceed 18% of the pre-IPO shares of the Predecessor after taking into account conversion of the Daewoong Convertible Notes.

Due to certain embedded features within the Daewoong Convertible Notes, the Predecessor elected to account for the Daewoong Convertible Notes, including the paid-in-kind principal and interest, and the embedded features at fair value at inception. Subsequent changes in fair value were recorded as a component of other income (loss) in the Predecessor's consolidated statements of operations and comprehensive income (loss) or as a component of other comprehensive income (loss) for changes to instrument-specific credit risk. As a result of electing the fair value option, any direct costs and fees related to the Daewoong Convertible Notes were expensed as incurred.

On July 29, 2022, the Predecessor entered into a Convertible Promissory Note Purchase Agreement (the "Agreement") between the Predecessor and Daewoong Co., LTD. and received \$30 million. The related note had a stated interest rate of 15.79% per annum. Such note was scheduled to mature on December 29, 2023 and had similar conversion terms to the Daewoong Convertible Notes. Such note could have been prepaid, in whole, without premium or penalty at any time prior to the maturity date.

During the period from January 1, 2023 to July 21, 2023, the Predecessor recognized \$3.7 million of income related to the decrease in the fair value of the Daewoong Convertible Notes. As of December 31, 2022, the principal amount outstanding (excluding the PIK Principal) under the Daewoong Convertible Notes was \$60 million, with an estimated fair value of \$53.5 million. The Daewoong Convertible Notes were converted into shares of the Successor's common stock at the Closing.

# Daewoong Convertible Notes (Successor)

On March 19, 2024, the Company entered into a subscription agreement with Daewoong (the "Subscription Agreement") relating to the sale and issuance by the Company of senior secured convertible notes (each, a "2024 Convertible Note" and together, the "2024 Convertible Notes") in the principal amount of up to \$15.0 million, which are convertible into shares of the Company's common stock, subject to certain conditions and limitations set forth in each Convertible Note. Each Convertible Note contains customary events of default, accrues interest at an annual rate of 15.79% and has a maturity date that is three years from the funding date, unless earlier repurchased, converted or redeemed in accordance with its terms prior to such date. The Company will use the net proceeds from each Convertible Note to support the late-stage clinical development of its lead product candidate ABP-450 and for general working capital purposes. Pursuant to the terms of the Subscription Agreement, on March 24, 2024, the Company issued and sold to Daewoong one Convertible Note in the principal amount of \$5.0 million, and on April 12, 2024, the Company issued and sold to Daewoong one Convertible Note in the principal amount of \$10.0 million.

On March 19, 2024, the Company entered into a Fourth Amendment to the License Agreement (the "License Agreement Amendment") with Daewoong, which amends that certain License and Supply Agreement, by and between the Company and Daewoong, dated December 20, 2019, as previously amended on July 29, 2022, January 8, 2023 and April 24, 2023 (the "License Agreement"). Pursuant to the terms of the License Agreement Amendment, the License Agreement will terminate if, over any six month period, (a) the Company ceases to commercialize ABP-450 in certain territories specified in the License Agreement and (b) the Company ceases to advance any clinical studies of ABP-450 in such territories. The License Agreement Amendment also provides that, in the event that the License Agreement is terminated for the foregoing reasons, Daewoong will have the right to purchase all Know-How (as defined in the License Agreement) related to ABP-450 for a price of \$1.00 (the "Termination Purchase Right"). The Termination Purchase Right will terminate and expire upon Daewoong's sale of 50% of its common stock, including common stock held by its affiliates and common stock that would be issued upon an Automatic Conversion or Optional Conversion (as defined in the Convertible Notes).

During the year ended December 31, 2024 (Successor), the Company recognized \$3.3 million of income related to the decrease in the fair value of the 2024 Daewoong Convertible Note. As of December 31, 2024, the principal amount outstanding under the 2024 Daewoong Convertible Note was \$15.0 million, with an estimated fair value of \$11.7 million.

#### Note 6. Fair Value Measurements

The Company measures fair value based on the prices that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The carrying value of cash, accounts payable and accrued liabilities approximate fair value because of the short-term nature of those instruments. The following are other financial assets and liabilities that are measured at fair value on a recurring basis.

#### Convertible Notes at Fair Value

Due to certain embedded features within the convertible notes, the Company elected the fair value option to account for its convertible notes, including any paid-in-kind principal and interest, and the embedded features.

During the year ended December 31, 2024 (Successor) and the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), the Company recognized \$3.3 million, \$(19.4) million and \$0 of income (expense) related to the decrease (increase) in fair value of the convertible notes. As of December 31, 2024, the principal amount outstanding under the convertible notes was \$15.0 million, with an estimated fair value of \$11.7 million. The Predecessor convertible notes were converted into shares of the Successor's common stock at the Closing. See Note 4 Related Party Transactions (Predecessor) and Note 5 Daewoong Convertible Notes for more information on those convertible notes.

The fair value of the convertible notes was determined based on Level 3 inputs using a scenario-based analysis that estimated the fair value of the convertible notes based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders, including various qualified financings, corporate transaction and dissolution scenarios. The significant unobservable input assumptions that can significantly change the fair value included (i) the discount rates, (ii) the timing of payments, and (iii) the probability of certain settlement scenarios.

During the year ended December 31, 2024 (Successor) and the period from January 1, 2023 to July 21, 2023 (Predecessor), the Company utilized discount rates ranging from 15% to 60%, reflecting changes in the Successor's and Predecessor's risk profile, time-to-maturity probability, and key terms to the convertible notes. As of the Closing, the fair value of the Predecessor convertible notes immediately prior to their conversion was based on the fair value of the Company's shares to be received by the holders using the market price of the shares at Closing.

# Forward Purchase Agreements (Successor)

On June 29, 2023, Priveterra and Old AEON entered into the Forward Purchase Agreements with each of (i) ACM ARRT J LLC ("ACM") and (ii) Polar Multi-Strategy Fund ("Polar") (each of ACM and Polar, individually, a "Seller", and together, the "Sellers") for OTC Equity Prepaid Forward Transactions. As described below, the Forward Purchase Agreements were terminated on March 18, 2024.

Pursuant to the terms of the Forward Purchase Agreements, the Sellers intended, but were not obligated, to purchase up to 104,167 shares of Priveterra Class A Common Stock in the aggregate concurrently with the Closing pursuant to each Seller's respective FPA Funding Amount PIPE Subscription Agreement.

Each Forward Purchase Agreement provided that a Seller would be paid directly the Prepayment Amount which was equal to an aggregate of \$66.7 million based on the product of (i) 87,154 shares of Priveterra Class A Common Stock (the "Additional Shares") and (ii) the redemption price per share of \$765.36.

On July 21, 2023, the Company was obligated to pay each Seller separately the Prepayment Amount required under its respective Forward Purchase Agreement, except that since the Prepayment Amount payable to a Seller was to be paid from the purchase of the Additional Shares by such Seller pursuant to the terms of its respective FPA Funding Amount PIPE Subscription Agreement, such amount was netted against such proceeds, with such Seller being able to reduce the purchase price for the Additional Shares by the Prepayment Amount. For the avoidance of doubt, any Additional Shares purchased by a Seller were to be included in the Number of Shares for its respective Forward Purchase Agreement for all purposes, including for determining the Prepayment Amount. Therefore, the aggregate Prepayment Amount of \$66.7 million was netted against the proceeds paid from the purchase of the Additional Shares in the aggregate by the Sellers pursuant to the FPA Funding Amount PIPE Subscription Agreements. The Company did not have access

to the Prepayment Amount immediately following the Closing and, pursuant to the termination of the Forward Purchase Agreements as described below related to the FPA termination, the Sellers will retain the Prepayment Amount in full, which may adversely affect our liquidity and capital needs. The Prepayment Amount of \$66.7 million was recorded at its present value of \$60.7 million as Subscription Receivables, which reduced stockholders' deficit on the Successor's consolidated balance sheet at December 31, 2023. The \$6 million difference between the subscription receivables and the present value of the subscription receivables at Closing was recorded as a loss "on the line" in the Successor's opening accumulated deficit (see Note 3 Forward Merger).

For the period from July 22, 2023 to December 31, 2023 (Successor), the Company recorded expense of \$8.4 million related to the increase in fair value of the derivatives to the Successor's consolidated statement of operations and comprehensive income (loss). The Company utilized the Monte-Carlo valuation model using expected volatility of 52.0% and risk-free rate of 4.48% and expected life of 1.56 years. As of December 31, 2023 (Successor), the fair value of the FPA was \$40.3 million, which was included within embedded forward purchase agreements and derivative liabilities on the consolidated balance sheet. As further discussed below, the FPA was terminated in March 2024.

Prior to the termination of the Forward Purchase Agreements, the redemption price per share in the Forward Purchase Agreements was subject to a reset price (the "Reset Price"). The Reset Price was initially the redemption price per share of \$765.36 per share. Beginning 90 days after the Closing, the Reset Price became subject to monthly resets, to be the lowest of (a) the then-current Reset Price, (b) \$765.36 and (c) the 30-day volume-weighted average price of the Company's Common Stock immediately preceding such monthly reset. The monthly resets of the Reset Price were subject to a floor of \$504.00 per share (the "Reset Price Floor"); however, if during the term of the Forward Purchase Agreements, the Company were to sell or issue any shares of Common Stock or securities convertible or exercisable for shares of Common Stock at an effective price of less than the Reset Price (a "Dilutive Offering"), then the Reset Price would have immediately reset to the effective price of such offering and the Reset Price Floor would be eliminated. Additionally, in the event of a Dilutive Offering, the maximum number of shares available under the Forward Purchase Agreements could have been increased if the Dilutive Offering occurred at a price below \$720.00 per shares. The maximum number of shares would have been reset to equal 104,167 divided by a number equal to the offering price in the Dilutive Offering divided by \$720.00.

Pursuant to the terms of the Forward Purchase Agreements, the "Valuation Date" would have been the earlier to occur of (a) the date that is two years after the Closing Date pursuant to the Business Combination Agreement; (b) the date specified by Seller in a written notice to be delivered to AEON at such Seller's discretion (which Valuation Date would not be earlier than the day such notice is effective) after the occurrence of any of (w) a VWAP Trigger Event, (x) a Delisting Event, or (y) a Registration Failure (defined terms in each of clauses (b)(w) through (b)(y), as described in further detail below) and (c) 90 days after delivery by AEON of a written notice in the event that for any 20 trading days during a 30 consecutive trading day-period that occurred at least 6 months after the Closing Date, the VWAP Price was less than the current Reset Price Floor of \$504.00 per share; provided, however, that the Reset Price would have been reduced immediately to any lower price at which the Company would have sold, issued or granted any shares or securities convertible or exchangeable into shares (other than, among other things, grants or issuances under the Company's equity compensation plans, any securities issued in connection with the Merger or any securities issued in connection with the FPA Funding Amount PIPE Subscription Agreements), subject to certain exceptions, in which case the Reset Price Floor would be eliminated.

On the Cash Settlement Payment Date, which would have been the tenth local business day following the last day of the valuation period commencing on the Valuation Date, a Seller was obligated to pay the Company a cash amount equal to (1) (A) a maximum of up to 104,167 shares of common stock (the "Number of Shares") as of the Valuation Date less the number of Unregistered Shares, multiplied by (B) the volume-weighted daily VWAP Price over the Valuation Period less (2) if the Settlement Amount Adjustment was less than the cash amount to be paid, the Settlement Amount Adjustment. The Settlement Amount Adjustment was equal to (1) the Number of Shares as of the Valuation Date multiplied by (2) \$144.00 per share, and the Settlement Amount Adjustment will be automatically netted from the Settlement Amount.

Based on the applicable guidance in ASC 480, ASC 815, ASC 505 and SAB 4E, the Company has determined that each of its Forward Purchase Agreements entered in connection with the Merger was a freestanding hybrid financial instrument comprising a subscription receivable and embedded features, which have been bifurcated and accounted for separately as derivative instruments. The Company recorded the derivatives as liabilities and measured them at fair value with the initial value of the derivative of \$32.3 million and the loss on issuance of \$6.0 million recorded as a loss "on the line" in the Successor's opening accumulated deficit (see Note 3 Forward Merger). Subsequent changes in the bifurcated derivatives are recorded in the Successor's consolidated statements of operations and comprehensive income (loss). For the period from July 22, 2023 to December 31, 2023 (Successor), the Company

recorded a loss related to the change in fair value of derivatives of \$8.4 million. The Company utilized the Monte-Carlo valuation model to value the forward purchase agreements at Closing date and as of December 31, 2023.

The following table summarizes the significant inputs as of the valuation dates:

	De	cember 31, 2023	 July 21, 2023
Stock Price	\$	518.40	\$ 780.48
Expected volatility		52.00%	55.00%
Risk-free interest rate.		4.48%	4.82%
Expected life (in years)		1.56	2.00
Expected dividend yield		_	

# Termination of Forward Purchase Agreements

On March 18, 2024, the Company and ACM ARRT J LLC ("ACM") entered into a termination agreement (the "ACM Termination Agreement") terminating that certain Forward Purchase Agreement, dated June 29, 2023, by and among the Company and ACM (the "ACM FPA"). The ACM Termination Agreement provides that ACM will retain 43,056 previously issued shares of common stock held by ACM pursuant to the ACM FPA and its respective subscription agreement (the "ACM Retained Shares"). ACM did not pay any cash to the Company for the ACM Retained Shares and retained all portions of the Prepayment Amount associated with the ACM Retained Shares.

On March 18, 2024, the Company and Polar entered into a termination agreement (the "Polar Termination Agreement") terminating that certain Forward Purchase Agreement, dated June 29, 2023, by and among the Company and Polar (the "Polar FPA"). The Polar Termination Agreement provides that Polar will retain 44,098 previously issued shares of common stock held by Polar pursuant to the Polar FPA and its respective subscription agreement (the "Polar Retained Shares"). Polar did not pay any cash to the Company for the Polar Retained Shares and retained all portions of the Prepayment Amount associated with the Polar Retained Shares.

As a result of the ACM Termination Agreement and Polar Termination Agreement, the Company recorded a charge to the consolidated statement of operations of \$20.3 million during the year ended December 31, 2024 to reverse the related subscription receivable and derivative liability on the accompanying consolidated balance sheet.

In connection with the negotiation of the Forward Purchase Agreements (and FPA Termination Agreements) and related subscription agreements, J.V.B. Financial Group, LLC, acting through its Cohen & Company Capital Markets division ("CCM"), provided certain consulting services, initially to Priveterra and subsequently to AEON, pursuant to an engagement letter, by and between the Company and CCM, dated July 27, 2023 and amended July 1, 2024 (the "CCM Engagement Letter"). On July 5, 2024, pursuant to the CCM Engagement Letter, the Company issued 5,556 shares of the Company's common stock to CCM.

## New Money PIPE Subscription Agreements

On June 29, 2023, Priveterra entered into separate subscription agreements (the "New Money PIPE Subscription Agreements") with each of ACM ASOF VIII Secondary-C LP ("ACM Investor"), the Polar Affiliate and certain other investors (collectively, the "New Money PIPE Investors"). Pursuant to the New Money PIPE Subscription Agreements, the New Money PIPE Investors subscribed for and purchased, and Priveterra issued and sold to the New Money PIPE Investors, on the Closing Date, an aggregate of 13,910 shares of Priveterra Class A Common Stock for a purchase price of \$504.00 per share, for aggregate gross proceeds of \$7.0 million (the "New Money PIPE Investment"). Certain affiliates of ACM Investor purchased 3,282 shares from third parties through a broker in the open market prior to the Closing, for which all redemption rights were irrevocably waived. Such redeemed shares were freely tradeable shares prior to the Closing, and the proceeds to the Company provided by such redeemed shares were netted against the \$3.5 million that ACM Investor was otherwise obligated to pay the Company under its New Money PIPE Subscription Agreement. Accordingly, Priveterra received \$3.5 million from Polar and \$0.9 million from ACM Investor (net of redeemed shares and fees) in connection with the New Money PIPE Subscription Agreements for the issuance of 13,910 shares. The Company recorded a loss of \$6.4 million on the line in the Successor's opening accumulated deficit related to issuance of common shares underlying the New Money PIPE Subscription Agreement equal to the market price of the stock on the Closing Date less the purchase price of \$504.00 per share.

# Committed Financing

In connection with the Merger, on January 6, 2023, Priveterra and Old AEON entered into separate subscription agreements for convertible notes with each of Alphaeon 1 LLC ("A1") and Daewoong Pharmaceuticals Co., Ltd. ("Daewoong") (collectively, the "Original Committed Financing Agreements"), pursuant to which A1 and Daewoong agreed to purchase, and Priveterra and Old AEON agreed to sell to each of them, up to \$15 million and \$5 million, respectively, aggregate of principal of interim convertible notes. Further, on June 8, 2023, Old AEON and Priveterra entered into a committed financing agreement with A1 (the "Additional Committed Financing Agreement"), pursuant to which A1 agreed to purchase, and Priveterra and Old AEON agreed to sell to A1, up to an additional \$20 million aggregate principal of interim convertible notes. Pursuant to such agreement, the Company issued \$14 million of interim convertible notes to A1 in the first and second quarters of 2023. The notes were subsequently measured at fair value under a fair value option election, with changes in fair value reported in earnings of the Predecessor (Old AEON). Conversion of the notes was contingent and automatically convertible on the Merger, and 30,920 shares of Priveterra Class A common stock were issued on the Closing Date in settlement of their conversion. The proceeds from the interim convertible notes were used to fund Old AEON's operations through the consummation of the Merger. Additionally, approximately \$25 million was received on the Closing Date in exchange for an aggregate of 49,604 shares of Priveterra Class A common stock at \$504.00 per share that were issued under a committed financing agreement between Priveterra, Old AEON, and each of two investors, A1 and Daewoong.

The Company recorded a loss of \$13.7 million on the line in the Successor's opening accumulated deficit related to issuance of common shares underlying the Committed Financing Agreements equal to the market price of the stock on the Closing Date less the purchase price of \$504.00 per share.

Contingent Consideration and Contingent Founder Shares (Successor)

As part of the Merger, certain Founder Shares and Participating Stockholders shares (together, "Contingent Consideration Shares"), as further discussed below, contain certain contingent provisions.

On April 27, 2023, Priveterra and Old AEON amended the Business Combination Agreement. Concurrently with the amendment to the Business Combination Agreement, Priveterra amended the Sponsor Support Agreement to include restriction and forfeiture provisions related to the Founder Shares. In addition following the Closing, certain AEON stockholders will be issued up to 222,653 additional shares of common stock.

Pursuant to the terms of the Sponsor Support Agreement, as amended, effective immediately after the Closing, 50% of the Founder Shares (i.e., 47,921 Founder Shares) (the "Contingent Founder Shares") were unvested and subject to the restrictions and forfeiture provisions set forth in this Sponsor Support Agreement. The remaining 50% of the Founder Shares and 100% of the Private Placement Warrants are not subject to such restrictions and forfeiture provisions. The Contingent Founder Shares shall vest, and shall become free of the provisions as follows:

- 13,890 of the Contingent Founder Shares (the "Migraine Phase 3 Contingent Founder Shares") shall vest upon the achievement of the conditions for the issuance of the Migraine Phase 3 Contingent Consideration Shares on or prior to the Migraine Phase 3 Outside Date;
- 13,890 of the Contingent Founder Shares (the "CD BLA Contingent Founder Shares") shall vest upon the achievement of the conditions for the issuance of the CD BLA Contingent Consideration Shares on or prior to the CD BLA Outside Date; and
- 20,141 of the Contingent Founder Shares (the "Episodic/Chronic Migraine Contingent Founder Shares") shall vest upon the earlier of (x) the achievement of the conditions for the issuance of the Episodic Migraine Contingent Consideration Shares on or before the Episodic Migraine Outside Date and (y) the achievement of the conditions for the issuance of the Chronic Migraine Contingent Consideration Shares on or before the Chronic Migraine Outside Date.

The Sponsor has agreed not to vote the Contingent Founder Shares during any period of time that such Contingent Founder Shares are subject to vesting.

Following the Closing, in addition to the consideration received at the Closing and as part of the overall consideration paid in connection with the Merger, certain holders of common stock in Old AEON (the "Participating AEON Stockholders") will be issued a portion of up to 222,653 additional shares of common stock, as follows:

- 13,996 shares of common stock, in the aggregate, if, on or before June 30, 2025 (as it may be extended, the "Migraine Phase 3 Outside Date"), the Company shall have commenced a Phase 3 clinical study for the treatment of chronic migraine or episodic migraine, which Phase 3 clinical study will have been deemed to commence upon the first subject having received a dose of any product candidate that is being researched, tested, developed or manufactured by or on behalf of the Company or any of its subsidiaries (any such product candidate, a "Company Product") in connection with such Phase 3 clinical study (such 13,996 shares of common stock, the "Migraine Phase 3 Contingent Consideration Shares"); and
- 55,659 shares of common stock, in the aggregate, if, on or before November 30, 2026 (as it may be extended, the "CD BLA Outside Date"), the Company shall have received from the FDA acceptance for review of the BLA submitted by the Company for the treatment of cervical dystonia (such 55,659 shares of common stock, the "CD BLA Contingent Consideration Shares");
- 55,659 shares of common stock, in the aggregate, if, on or before June 30, 2029 (as it may be extended, the "Episodic Migraine Outside Date"), the Company shall have received from the FDA acceptance for review of the BLA submitted by the Company for the treatment of episodic migraine (such 55,659 shares of common stock, the "Episodic Migraine Contingent Consideration Shares"); provided that in the event the satisfaction of the conditions for the issuance of the Episodic Migraine Contingent Consideration Shares occurs prior to the satisfaction of the conditions for the issuance of the Chronic Migraine Contingent Consideration Shares, then the number of Episodic Migraine Contingent Consideration Shares shall be increased to 152,998 shares of common stock; and
- 97,339 shares of common stock, in the aggregate, if, on or before June 30, 2028 (as it may be extended, the "Chronic Migraine Outside Date", and together with the Migraine Phase 3 Outside Date, the CD BLA Outside Date and the Episodic Migraine Outside Date, the "Outside Dates"), the Company shall have received from the FDA acceptance for review of the BLA submitted by AEON for the treatment of chronic migraine (such 97,339 shares of common stock, the "Chronic Migraine Contingent Consideration Shares"); provided that in the event that the number of Episodic Migraine Contingent Consideration Shares is increased to 152,998, then the number of Chronic Migraine Contingent Consideration Shares shall be decreased to zero and no Contingent Consideration Shares will be issued in connection with the satisfaction of the conditions to the issuance of the Chronic Migraine Contingent Consideration Shares.
- In the event that the Company licenses any of its products (except in connection with migraine or cervical dystonia indications) to a third-party licensor for distribution in the U.S. market (a "Qualifying License") prior

to the satisfaction of (x) the conditions for the issuance of the Episodic Migraine Contingent Consideration Shares and (y) the conditions for the issuance of the Chronic Migraine Contingent Consideration Shares, then upon the entry of AEON into such Qualifying License, 27,992 shares of common stock shall become due and payable to Participating Stockholders and the number of Episodic Migraine Contingent Consideration Shares and (A) the number of Episodic Migraine Contingent Consideration Shares shall be reduced by 13,996 or by 27,992 and (B) the number of Chronic Migraine Contingent Consideration Shares shall be reduced by 13,996, but not below zero.

The Company classifies the Contingent Consideration as a liability on the Successor's consolidated balance sheets and remeasures at each reporting period with changes to fair value recorded to the Successor's consolidated statements of operations and comprehensive income (loss).

The Company utilized the Probability-Weighted Expected Return Method (PWERM) model to value the contingent consideration based on earnout milestones, probability of forfeiture and success scenarios. For the year ended December 31, 2024 and the successor period July 22, 2023 to December 31, 2023, the Company recognized \$100.8 million and \$52.8 million, respectively, of income related to the change in fair value of contingent consideration on the Successor's consolidated statements of operations and comprehensive income (loss), and relates to the change in probabilities of achieving certain scenarios following the clinical results released in the second quarter of 2024 and changes in the Company's stock price during the period. As of December 31, 2024 (Successor), the contingent consideration liability was \$3.5 million.

# Warrants (Successor)

Upon the Closing, 201,112 warrants that were initially issued by Priveterra in February 2021, consisting of 127,788 public warrants sold in the IPO and 73,334 warrants issued in a concurrent private placement, were outstanding. The terms of the warrants are governed by a Warrant Agreement dated February 8, 2021 between the Company (then known as Priveterra Acquisition Corp.) and Continental Stock Transfer & Trust Company (the "Warrant Agreement").

The warrants are accounted for as a liability at the Closing with changes in the fair value through recorded to the Successor's consolidated statement of operations. The Company utilized the Black-Scholes model (Level 3) to value the warrants at \$1.2 million as of December 31, 2024. The Company utilized the publicly reported market price of the public warrants (Level 1) to value the warrant liability at \$1.4 million as of December 31, 2023 (Successor). For the year ended December 31, 2024 and the Successor period from July 22, 2023 to December 31, 2023, the (expense) income from the change in fair value of warrants was \$(14.7) million and \$2.3 million, respectively.

The following table summarizes the significant inputs as of the valuation dates:

	December 31, 2024		De	cember 31, 2023
	(	Level 3)		(Level 1)
Stock Price	\$	38.88	\$	518.40
Expected volatility		155.00%		_
Risk-free interest rate.		4.23%		
Expected life (in years)		0.56		
Expected dividend yield				

### Public warrants

Each whole public warrant entitles the holder to purchase one share of the Company's common stock at a price of \$828.00 per share. The public warrants became exercisable 30 days after the completion of the Merger, and will expire at 5:00 p.m., New York City time, on July 21, 2028, the five-year anniversary of the completion of the Merger, or earlier upon redemption or liquidation. Warrant holders may, until such time as there is an effective registration statement and during any period when the Company has failed to maintain an effective registration statement covering the shares of the Company's common stock issuable upon exercise of the warrants, exercise warrants on a "cashless" basis" in accordance with Section 3(a)(9) of the Securities Act or another exception. When exercised on a cashless basis, the number of shares received per warrant is capped at 1.0.

The Company may call the public warrants for redemption for cash:

- in whole and not in part;
- at a price of \$0.72 per warrant;
- upon not less than 30 days' prior written notice of redemption to each warrant holder (the "30-day redemption period");
- if, and only if, there is an effective registration statement under the Securities Act of 1933 covering the issuance of the shares of common stock issuable upon exercise of the warrants, and a current prospectus relating thereto, available through the 30-day redemption period; and
- if, and only if, the closing price of the Company's common stock equals or exceeds \$1,296.00 per share (as adjusted for stock splits, stock capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending three business days before the Company sends to the notice of redemption to the warrant holders.

The Company may also call the public warrants for redemption:

- in whole and not in part;
- at \$7.20 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares to be determined by reference to a table in the Warrant Agreement, based on the redemption date and the "fair market value" (as defined in the Warrant Agreement) of common stock except as otherwise described below; and
- if, and only if, the closing price of the Company's common stock equals or exceeds \$720.00 per share (as adjusted for stock splits, stock capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending three business days before the Company sends to the notice of redemption to the warrant holders.

# Private placement warrants

Each private placement warrant was identical to the public warrants initially sold by Priveterra in the IPO, except that the private placement warrants, so long as they are held by the Sponsor or its permitted transferees, (i) will not be redeemable by the Company and (ii) may be exercised by the holders on a cashless basis.

### Warrant exercises

On March 29, 2024, the Company delivered notice of redemptions to warrant holders with a redemption date of April 29, 2024 for a cashless redemption of the Company's outstanding public warrants. The number of shares of common stock that each exercising warrant holder received by virtue of the cashless exercise (instead of paying the \$828.00 per Public Warrant cash exercise price) was calculated in accordance with the terms of the Warrant Agreement. Any remaining unexercised public warrants on the redemption date were cancelled and the public warrant holders received the redemption price of \$7.20 for each public warrant.

During the year ended December 31, 2024, an aggregate of 142,829 warrants were exercised on a cashless basis for 27,310 shares of common stock, with an impact to additional paid in capital of \$15.0 million. Additionally, the Company paid \$21 thousand in April 2024 related to the cancellation of the remaining 2,881 public warrants on the redemption date.

A summary of activity of the Company's issued and outstanding public warrants for the year ended December 31, 2024 (Successor) is as follows:

	Public	Private	1 otai
Issued and Outstanding, January 1, 2024	127,778	73,334	201,112
Number of warrants exercised	(124,897)	(17,931)	(142,828)
Number of warrants cancelled	(2,881)	-	(2,881)
Issued and Outstanding, December 31, 2024		55,403	55,403

# Medytox Top-off Right

The Predecessor entered into a settlement agreement with Medytox, Inc. ("Medytox") (the "Settlement Agreement"), effective as of June 21, 2021, as amended on May 5, 2022. Pursuant to the Settlement Agreement, among other things, the Predecessor agreed to enter into a share issuance agreement with Medytox pursuant to which the Predecessor issued 26,680,511 shares of Old AEON common stock, par value \$0.0001 per share, to Medytox. The Settlement Agreement stated that in the event the shares of Old AEON common stock the Predecessor issued to Medytox represent less than 10% of the Predecessor's total outstanding shares immediately prior to the consummation of the Merger (the "Target Ownership"), the Company will issue additional shares of Old AEON common stock to Medytox sufficient to cause Medytox to achieve the Target Ownership (the "Top-off Right").

Because the shares of Old AEON common stock due to be issued to Medytox represented less than 10% of the Predecessor's total outstanding shares immediately prior to consummation of the Merger, the Predecessor issued additional shares of Old AEON common stock (the "Top-off Shares") to Medytox sufficient to cause Medytox to achieve the Target Ownership immediately prior to the Merger to the Top-off Right.

Based on the terms of the Settlement Agreement, the Top-off Right is a freestanding financial instrument, and is accounted for as a derivative liability pursuant to ASC 815. Accordingly, the Company recognized a loss of \$11.8 million in the Predecessor period, reflecting the change in fair value through the Closing Date. At the Closing, the derivative liability was derecognized, and the issuance of the Top-off Shares was recognized as purchase consideration in the Successor's opening additional paid-in capital (see Note 3 Forward Merger).

# Summary of Recurring Fair Value Measurements

The following details the Company's recurring measurements for assets and liabilities at fair value on the consolidated balance sheets as of December 31, 2024 (in thousands):

	Notes Liab		Warrant Liabilities (Level 3)	Contingent onsideration (Level 3)	Agr M I	Forward Purchase reement and ake Whole Derivative (Level 3)	
Successor							
Balance, January 1, 2024	\$	-	\$	1,447	\$ 104,350	\$	41,043
Issuance of convertible notes		15,000		-	-		-
Change in fair value		(3,311)		14,719	(100,809)		(663)
Warrant cashless exercise		_		(14,979)	<u>-</u>		-
Termination of forward purchase agreements		-		_	-		(40,380)
Balance, December 31, 2024	\$	11,689	\$	1,187	\$ 3,541	\$	-

Emboddod

The following details the Company's recurring measurements for assets and liabilities at fair value on the consolidated balance sheets as of December 31, 2023 (in thousands):

	Convertible Notes (Level 3)	Warrant Liabilities (Level 1)	Contingent Consideration (Level 3)	Embedded Forward Purchase Agreement and Make Whole Derivative (Level 3)
Predecessor	Ф. 101.000	Φ.	Ф	Ф
Balance, December 31, 2022	\$ 131,292	\$ -	\$ -	\$ -
Issuance of convertible notes	14,000	-	-	-
Change in fair value	19,359	-	-	-
Conversion to common shares	(164,651)	-	-	-
Balance, July 21, 2023	-	-	-	-
Successor				
Balance, July 22, 2023	-	3,765	157,100	32,677
Additions	-	-	-	-
Change in fair value	_	(2,318)	(52,750)	8,366
Balance, December 31, 2023	\$ -	\$ 1,447	\$ 104,350	\$ 41,043

# Note 7. Commitments and Contingencies

# **Operating Leases**

In December 2021, the Predecessor entered into a three-year non-cancellable lease for office space. The lease was extended for an additional five years in March 2024 by the Successor. The lease does not include variable or contingent lease payments. An operating lease asset and liability are recognized based on the present value of the remaining lease payments discounted using the Successor's incremental borrowing rate. Lease expense is recognized on a straight-line basis over the lease term.

The following table summarizes supplemental balance sheet information related to the operating lease as of December 31, 2024 (in thousands):

Minimum lease payments by fiscal year	
2025	\$ 175
2026	297
2027	307
2028	318
2029	329
Thereafter	_
Total future minimum lease payments	 1,426
Less: Imputed interest	(160)
Present value of lease payments	 1,266
Less: Current portion (included in other accrued expenses)	(121)
Noncurrent operating lease liability	\$ 1,145
Operating lease right-of-use asset	\$ 1,288
Remaining lease term in years	5.0
Discount rate	4.3 %

The following table summarizes supplemental disclosures of operating cost and cash flow information related to operating leases for the periods indicated (in thousands):

		Year Ended				
		December 31,				
		2024 2023				
	Su	iccessor	Successor July 22 to December 31		Predecessor January 1 to July 22	
Cost of operating leases	\$	260	\$	153	\$	122
Cash paid for operating leases		319		180		129

# Daewoong License and Supply Agreement

On December 20, 2019, the Predecessor entered the Daewoong Agreement, pursuant to which Daewoong agreed to manufacture and supply ABP-450 and grant the Company an exclusive license for therapeutic indications to import, distribute, promote, market, develop, offer for sale and otherwise commercialize and exploit ABP-450 in the United States, the European Union, the United Kingdom, Canada, Australia, Russia, the Commonwealth of Independent States and South Africa (collectively the "covered territories").

Daewoong supplies the Company with ABP-450 at an agreed-upon transfer price, with no milestone or royalty payments and no minimum purchase requirements. Daewoong is responsible for all costs related to the manufacturing of ABP-450, including costs related to the operation and upkeep of its manufacturing facility, and the Company is responsible for all costs related to obtaining regulatory approval, including clinical expenses, and commercialization of ABP-450. The Company's exclusivity is subject to its exercise of commercially reasonable efforts to: (i) achieve all regulatory approvals necessary for ABP-450 to be marketed in the territory for therapeutic indications and (ii) commercialize ABP-450 in the territory for therapeutic indications. During the term of the Daewoong Agreement, the Company cannot purchase, sell or distribute any competing products in a covered territory or sell ABP-450 outside a covered territory.

The initial term of the Daewoong Agreement is from December 20, 2019 to the later of (i) the fifth anniversary of approval from the relevant governmental authority necessary to market and sell ABP-450 or (ii) December 20, 2029, and automatically renews for unlimited additional three-year terms, provided the Daewoong Agreement is not earlier terminated. The Daewoong Agreement will terminate upon written notice by either the Company or Daewoong upon a continuing default that remains uncured within 90 days (or 30 days for a payment default) by the other party, or without notice upon the bankruptcy or insolvency of the Company.

The Company has recorded \$0.2 million as a liability in accounts payable on the consolidated balance sheets as of December 31, 2024 (Successor) and accrued a de minimus amount for ABP-450 supplies in accrued expenses on the consolidated balance sheets as of December 31, 2023 (Successor).

# Legal Proceedings

The Company, from time to time, is involved in various litigation matters or regulatory encounters arising in the ordinary course of business that could result in unasserted or asserted claims or litigation. Other than as described below, the Company is not subject to any currently pending legal matters or claims that would have a material adverse effect on its accompanying financial position, results of operations or cash flows.

On September 18, 2023, Odeon Capital Group LLC ("Odeon") filed a lawsuit against the Company in the Supreme Court of the State of New York, alleging that the Company failed to pay Odeon's deferred underwriting fee of \$1.25 million. Odeon claims that it served as the underwriter for Priveterra Acquisition Corp., the special purpose acquisition company with which Old AEON merged with and into in July 2023. Odeon seeks monetary damages for the full amount of its claimed underwriting fee, punitive damages, attorneys' fees and other amounts. In November 2023, the Company filed a motion to dismiss certain claims included in Odeon's complaint. In April 2024, the Company successfully obtained a dismissal of Odeon's non-breach of contract claims, including the tort claims, breach of covenant claim and associated punitive damages claim. Odeon's breach of contract claim is proceeding, with each party filing a summary judgment motion in March 2025, which the court is expected to decide upon in the coming months.

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. See Note 2 Summary of Significant Accounting Policies for additional information.

### Note 8. Income Taxes

The Company's income (loss) before income taxes for the periods presented in the statement of operations was entirely generated from its U.S. operations. As a result of its continuing taxable losses, the Company had no provision for income taxes for the year ended December 31, 2024 and the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor).

As of December 31, 2024 and 2023, the Company had federal net operating loss ("NOL") carryforwards of \$112.1 million and \$87.3 million, respectively, which will begin to expire in 2036. The Company had state NOLs of \$140.5 million and \$116.2 million as of December 31, 2024 and 2023, respectively, which will begin to expire in 2034. As of December 31, 2024 and 2023, the Company has federal research and development ("R&D") credit carryforwards of \$6.9 million and \$6.1 million, respectively, which will begin to expire in 2039. As of December 31, 2024 and 2023, the Company also has California R&D credit carryforwards of \$5.0 million and \$4.4 million, respectively, which have an indefinite carryforward period.

In general, if the Company experiences a greater than 50 percentage point aggregate change in ownership of certain significant stockholders over a three-year period (a "Section 382 ownership change"), utilization of its pre-change NOL carryforwards and the R&D credit carryforwards is subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and similar state laws. The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change, subject to certain adjustments, by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards and R&D credit carryforwards before utilization and may be material. As of December 31, 2024, the Company has not determined to what extent a potential ownership change will impact the annual limitation that may be placed on the Company's utilization of its NOL carryovers and R&D credit carryforwards. Due to the existence of the valuation allowance, limitations created by ownership changes, if any, will not impact the Company's effective tax rate.

The components of deferred tax assets and liabilities were as follows (in thousands):

	December 31,				
		2024		2023	
Deferred tax assets:					
Accrued compensation	\$	283	\$	271	
Accrued other expense		469		_	
Stock compensation		1,941		1,647	
Start-up costs and other intangibles		10,834		12,230	
Net operating losses		35,966		28,613	
Lease liability		378		83	
Other deferred assets		24		23	
Capitalized Research and Development Expenses		11,090		11,264	
•	-	60,985		54,131	
Less: valuation allowance		(59,560)		(53,978)	
Total deferred tax assets		1,425		153	
Deferred tax liabilities:					
Depreciation		(53)		(75)	
ROU Asset		(384)		(78)	
Convertible notes.		(988)		_	
Total deferred tax liabilities	-	(1,425)		(153)	
Net deferred income taxes	\$		\$		

A reconciliation of the difference between the provision (benefit) for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows:

	December 31,	
	2024	2023
Income tax at statutory rate	21.0 %	21.0 %
Convertible notes		(1.1)
Contingent consideration	(50.4)	2.9
Forward purchase agreements	9.8	(1.0)
Warrants	7.4	0.1
Stock compensation	1.0	(0.2)
Officers compensation	1.4	(0.5)
Transaction costs	0.5	(0.8)
IPR&D	_	(19.0)
Change in valuation allowance	9.3	(1.4)
Effective tax rate	0.0 %	0.0 %
-		

A reconciliation of unrecognized tax benefits at the beginning and end of 2024 and 2023 is as follows (in thousands):

	December 31,			
	2024		2023	
Balance, beginning of year	\$	14,670	\$	11,061
Increases due to current year tax positions		1,445		3,609
Decreases due to prior year tax positions		_		
Balance, end of year	\$	16,115	\$	14,670

The Company has considered the amounts and probabilities of the outcomes that can be realized upon ultimate settlement with the tax authorities and determined unrecognized tax benefits should be established of \$16.1 million and \$14.7 million as of December 31, 2024 and 2023, respectively. The Company's effective income tax rate would not be impacted if the unrecognized tax benefits are recognized. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. There were no accrued interest and penalties associated with uncertain tax positions as of December 31, 2024. The Company's tax returns for all years since inception are open for audit.

The Company measures deferred tax assets and liabilities using enacted tax rates that will apply in the years in which the temporary differences are expected to be recovered or paid.

#### Note 9. Common Stock

### Predecessor

As of December 31, 2022 (Predecessor), the Predecessor's certificate of incorporation, as amended and restated, authorized the Predecessor to issue up to 207,450,050 shares of common stock at a par value of \$0.0001 per share. As of December 31, 2022 (Predecessor), 138,848,177 shares were issued and 138,825,356 shares were outstanding. The holders of common stock were entitled to receive dividends whenever funds are legally available, when and if declared by the Predecessor's board of directors, subject to the prior rights of the holders of the Predecessor's convertible preferred stock. As of December 31, 2022 (Predecessor), no cash dividend had been declared to date. Each share of common stock was entitled to one vote. The number of authorized shares of common stock could be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of shares of preferred stock and common stock, voting together as a single class.

#### Successor

The Successor's certificate of incorporation, as amended and restated, authorized the Company to issue up to 500,000,000,000 shares of common stock at a par value of \$0.0001 per share. The holders of common stock are entitled to receive dividends whenever funds are legally available, when and if declared by the Company's Board of Directors. As of December 31, 2024 (Successor), no cash dividend has been declared to date. Each share of common stock is entitled to one vote. See to Note 3 Forward Merger for more information on the number of shares of common stock outstanding immediately following the Merger.

### Common Stock Reserved

The table below summarizes the Company's reserved common stock for further issuance as of December 31, 2024 (Successor) and December 31, 2023 (Successor):

	December 31,	
	2024	2023
Stock options issued and outstanding	98,971	53,455
Restricted stock units (unvested)	25,613	14,075
Shares available for future issuance under the stock incentive plan	25,818	49,118
Warrants	55,403	201,112
Contingent consideration	222,653	222,653
Convertible notes	399,128	<u> </u>
Total common stock reserved.	827,586	540,413

## ATM Offering of Common Stock

On August 14, 2024, the Company entered into an "at-the-market" sales agreement with Leerink Partners LLC ("Leerink Partners") relating to an at-the-market offering program (the "ATM"), pursuant to which the Company may offer and sell, from time to time at its sole discretion, shares of common stock, registered pursuant to a shelf registration statement on Form S-3 that the Securities and Exchange Commission (the "SEC") declared effective on August 21, 2024, having aggregate gross proceeds of up to \$50.0 million through Leerink Partners as sales agent. Under the ATM, Leerink Partners is entitled to commission at a rate equal to 3.0% of the gross proceeds from sales of shares of common stock under the ATM. As of December 31, 2024, the Company issued 2,241 shares under the ATM for net proceeds of \$147 thousand and approximately \$49.8 million of common stock remained available to be sold under the ATM. The Company may cancel its at-the-market program at any time upon prior notice, pursuant to its terms.

# 2023 Employee Stock Purchase Plan ("ESPP")

The 2023 Employee Stock Purchase Plan assists eligible employees in acquiring a stock ownership interest of the Company's common stock in consideration of the participating employees' continued services. Eligible employers will be entitled to purchase, by means of payroll deductions, limited amounts of the Company's common stock at a discount during periodic offering periods. There were 6,780 shares initially reserved for issuance under the 2023 ESPP, which shall automatically increase on January 1 of each calendar year beginning and including January 1, 2024 and ending on and including January 1, 2033, by an amount equal to the lesser of (i) 1.0% of the total number of shares of common stock issued and outstanding on January 1 of the year in which such increase is to occur, or (ii) such smaller number of shares of common stock as may be established by the Board of Directors. As of December 31, 2024, there were 12,619 shares available for issuance. There have been no shares issued under the 2023 ESPP.

### Note 10. Share-based Compensation Stock Incentive Plans

### AEON 2013 Stock Incentive Plan (Predecessor)

In 2013, the Predecessor established its 2013 Stock Incentive Plan (the "2013 Stock Incentive Plan") as amended from time to time, that provides for the granting of nonqualified stock options, restricted stock and stock appreciation rights to employees, members of the board of directors and non-employee consultants. The 2013 Stock Incentive Plan provides for stock options to be granted with exercise prices not less than the estimated fair value of the Predecessor's common stock, and incentive options to be granted to individuals owning more than 10% of the total combined voting power of all classes of stock of the Predecessor with exercise prices not less than 110% of the estimated fair value of the Predecessor's common stock on the date of grant. Stock options granted generally expire ten years after their original date of grant and generally vest between three years to four years with 25% vesting on the first anniversary of the date of grant and then monthly vesting after that. Stock options granted to a 10% stockholder are exercisable up to five years from the date of grant. Restricted stock awards granted generally become fully vested between one to three years. Upon the Closing, the 2013 Stock Incentive Plan was terminated and the stock options were cancelled.

The following table summarizes stock option activity under the Predecessor's 2013 Stock Incentive Plan prior to the Closing:

	Number of Shares	 Weighted Average Exercise Price
<u>Predecessor</u>		
Outstanding, January 1, 2023	9,694,890	\$ 1.53
Options granted	_	
Options forfeited		
Options cancelled in connection with Merger	(9,694,890)	\$ 1.53
Outstanding, July 21, 2023		_
Exercisable, July 21, 2023.		_

All awards were fully vested prior to 2022. As such during the periods from January 1, 2023 to July 21, 2023 (Predecessor), the Predecessor did not recognize share-based compensation expense related to stock options granted under the 2013 Stock Incentive Plan. As of December 31, 2023, there was no unrecognized compensation expense related to non-vested stock options.

#### 2019 Incentive Award Plan

In June 2019, ABP Sub Inc., the Predecessor's wholly-owned subsidiary, established its 2019 Incentive Award Plan (the "2019 Incentive Award Plan"), as amended from time to time, that provides for the granting of incentive and nonqualified stock options, restricted stock units ("RSU"), restricted stock and stock appreciation rights to its employees, members of the Board of Directors and non-employee consultants. The 2019 Incentive Award Plan provides for stock options to be granted with exercise prices not less than the estimated fair value of the Predecessor's common stock, and incentive options to be granted to individuals owning more than 10% of the total combined voting power of all classes of stock of the Predecessor with exercise prices not less than 110% of the estimated fair value of the Predecessor's common stock on the date of grant. Stock options granted generally expire ten years after their original date of grant and generally vest between three years to four years with 25% vesting on the first anniversary of the date of grant and then monthly vesting after that. Stock options granted to a 10% stockholder are exercisable up to five years from the date of grant. Restricted stock awards granted generally become fully vested between one to three years.

In connection with the Merger, the Successor assumed the 2019 Incentive Award Plan and all options and RSU awards that were outstanding immediately prior to the Merger were converted into substantially similar awards covering shares of the Successor's common stock based on a conversion ratio of approximately 1.078 to 1 share. Additionally, the exercise price for the awards were repriced to \$720.00 for all options. The options and RSU awards have lock-up provisions of one year from the Closing. The fair value of the replacement awards that were vested, based on the value immediately prior to the Merger, of \$13.3 million were included as purchase consideration (see Note 3 Forward Merger for additional information). The remaining value of the replacement awards will be recognized in the successor period as compensation expense over the remaining vesting period, which includes stock-based compensation expense of \$1.0 million recorded in the successor period for the impact of the stock option repricing.

Prior to the consummation of the Merger, a total of 237,500 shares of ABP Sub Inc. common stock were available for issuance under the 2019 Incentive Award Plan. Following the effective date of the 2023 Plan, in the event that an outstanding award expires or is cancelled for any reason, the shares allocable to the unexercised or cancelled portion of such award from the 2019 Incentive Award Plan will be added back to the shares of common stock available for issuance under the 2023 Incentive Award Plan.

At the Closing, ABP had granted options to purchase a total of 45,130 ABP Sub options which converted into options to purchase 48,844 shares of the Company's common stock, and a total of 15,059 RSU awards, which converted into RSU awards covering 16,250 shares of the Company's common stock. Of such RSU awards, 1,778 RSUs accelerated vesting concurrently with the Merger. As such, the Company included an additional \$1.8 million in purchase consideration (see Note 3 Forward Merger for additional information). Additionally, of such RSU awards, 6,481 RSU's contained performance-based vesting criteria based on the achievement of the same milestones as the contingent consideration (see Note 6 Fair Value Measurements for additional information). Upon designation of a probable milestone, the Company expenses the proportionate RSU's over the vesting term, calculated as the period from the date the milestone was determined to be probable and the expected achievement date of the milestone. For the year ended December 31, 2024 and the period from July 22, 2023 to December 31, 2023 (Successor), the Company has recognized \$0.3 million and \$0.4 million, respectively, in selling, general and administrative expenses and a de minimus amount in research and development expenses associated with such performance based RSU's in the Successor's consolidated statement of operations.

The following table summarizes stock option activity in 2024 under 2019 Incentive Award Plan:

	Number of Shares	Weighted Average Exercise Price
Successor		
Outstanding, January 1, 2024	48,844	\$ 720.00
Options granted	_	
Options forfeited	(889)	\$ 720.00
Outstanding, December 31, 2024	47,955	\$ 720.00
Exercisable, December 31, 2024	39,302	\$ 720.00

There were no options granted in the 2019 Incentive Plan during 2023, and no options will be granted from this plan after the Closing.

As of December 31, 2024 and December 31, 2023, the weighted average remaining contractual life of options outstanding and options exercisable was 6.0 years and 7.1 years.

During the year ended December 31, 2024 (Successor) and the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), the Company recognized \$2.9 million, \$2.7 million and \$2.4 million, respectively, of share-based compensation expense related to stock options granted.

As of December 31, 2024 and December 31, 2023, total unrecognized compensation expense related to nonvested stock options was \$1.8 million and \$4.9 million, respectively, which is expected to be recognized over the weighted-average remaining requisite service period of 4 months and 10 months, respectively.

The following table summarizes restricted stock units activity in 2024 under the 2019 Incentive Award Plan:

	Number of Shares	 Weighted Average Grant Date Fair Value
Successor		
Outstanding, January 1, 2024	14,075	\$ 780.48
Granted	_	_
Vested	(2,222)	\$ 780.48
Forfeited	(455)	\$ 780.48
Outstanding, December 31, 2024	11,398	\$ 780.48

During the year ended December 31, 2024 (Successor) and the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), the Company recognized \$1.3 million, \$0.5 million and \$0.8 million, respectively, of share-based compensation expense related to restricted stock units granted.

As of December 31, 2024 and December 31, 2023, total unrecognized compensation expense related to nonvested restricted stock units was \$7.3 million and \$9.6 million, respectively, which is expected to be recognized over the weighted-average remaining requisite service period of 21 months and 31 months, respectively. The unrecognized compensation expense with the earnout criteria will be recognized when the milestones are determined to be probable over the RSUs vesting term, calculated as the period from the date the milestone was determined to be probable and the expected achievement date of the milestone.

# AEON Biopharma Inc 2023 Incentive Award Plan

In connection with the Merger, the Company's Board adopted, and its stockholders approved, the 2023 Plan, which became effective upon the consummation of the Merger, that provides for the granting of nonqualified stock options, restricted stock and stock appreciation rights to employees, members of the Board and non-employee consultants. The 2023 Plan will remain in effect until July 3, 2033, the tenth anniversary of the date the Company's stockholders approved the 2023 Plan, unless earlier terminated. Stock options granted generally expire ten years after their original date of grant and generally vest between three years to four years with equal installments vesting on each anniversary of the grant date, subject to continued service through the applicable vesting date.

The initial aggregate number of shares of the Company's common stock available for issuance under the 2023 Plan is equal to (a) 53,332 shares of common stock and (b) any shares which, as of the effective date of the 2023 Plan, are subject to an award outstanding under the ABP 2019 Plan (each, a "Prior Plan Award"), and which, on or following the effective date of the 2023 Plan, become available for issuance under the 2023 Plan as provided in the 2023 Plan. In addition, the number of shares of common stock available for issuance under the 2023 Plan will be annually increased on January 1 of each calendar year beginning in 2024 and ending in 2033 by an amount equal to the lesser of (i) 4% of the number of fully-diluted number of shares outstanding on the final day of the immediately preceding calendar year or (ii) such other number of shares as is determined by the Board. Any shares issued pursuant to the 2023 Plan may consist, in whole or in part, of authorized and unissued common stock, treasury common stock or common stock purchased on the open market. As of December 31, 2024, there were 13,199 shares of common stock available for issuance under the 2023 Plan.

The following table summarizes stock options activity in 2024 under the 2023 Incentive Award Plan:

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2024	4,611	\$ 393.84
Options granted	47,634	\$ 242.14
Options forfeited	(1,229)	\$ 811.13
Outstanding, December 31, 2024	51,016	\$ 242.14
Exercisable, December 31, 2024	9,847	\$ 108.16

The weighted average per share fair value of options granted in 2024 and 2023 was \$135.50 and \$229.29, respectively. The weighted average remaining contractual life of options outstanding and options exercisable as of December 31, 2024 and December 31, 2023 was 9.5 years and 9.6 years, respectively.

During the year ended December 31, 2024 (Successor) and the period from July 22, 2023 to December 31, 2023 (Successor), the Company recognized \$1.6 million and \$0.1 million, respectively, of share-based compensation expense related to stock options granted. As of December 31, 2024 and December 31, 2023, total unrecognized compensation expense related to nonvested stock options was \$5.3 million and \$0.9 million, respectively, which is expected to be recognized over the weighted-average remaining requisite service period of 19 months and 35 months, respectively.

The following table summarizes restricted stock units activity in 2024 under the 2023 Incentive Award Plan:

	Number of Shares	(	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2024			
Granted	14,215	\$	60.05
Vested	_		
Forfeited			_
Outstanding, December 31, 2024	14,215	\$	60.05

During the year ended December 31, 2024 (Successor), the Company recognized \$0.1 million of share-based compensation expense related to restricted stock units granted.

As of December 31, 2024 (Successor), total unrecognized compensation expense related to nonvested restricted stock units was \$0.7 million, which is expected to be recognized over the weighted-average remaining requisite service period of 20 months.

# Share-based Compensation Expense and Valuation Information

The Company accounts for the measurement and recognition of compensation expense for all share-based awards based on the estimated fair value of the awards. The fair value of share-based awards is amortized on a straight-line basis over the requisite service period. The Company records share-based compensation expense net of actual forfeitures.

During the year ended December 31, 2024 (Successor) and the periods from January 1, 2023 to July 21, 2023 (Predecessor) and July 22, 2023 to December 31, 2023 (Successor), the Company recognized \$4.7 million, \$2.8 million and \$3.1 million, respectively, of share-based compensation expense in selling, general and administrative expenses, respectively, and \$1.5 million, \$0.4 million and \$0.8 million, respectively, in research and development expenses in the accompanying consolidated statements of operations and comprehensive income (loss).

The fair value of stock options under the 2019 Plan and 2023 Plan was estimated using the following assumptions:

	Year Ended December 31,	
	2024	2023
Expected volatility	47% – 87%	39% – 58%
Risk-free interest rate.	3.7% - 4.3%	4.1% - 4.4%
Expected life (in years)	5.27 - 6.25	3.00 - 6.25
Expected dividend yield	_	_

Fair Value of the Underlying Common Stock. For the Predecessor period, since the Predecessor's common stock was not traded in a public stock market exchange, the Board considered numerous factors including new business and economic developments affecting the Predecessor and independent appraisals, when appropriate, to determine the fair value of the Predecessor's common stock. Independent appraisal reports were prepared using valuation techniques, such as discounted cash flow analyses, from which a discount factor for lack of marketability was applied. This determination of the fair value of the common stock was performed on a contemporaneous basis. The Board determined the Company's common stock fair value on an as needed basis. For Successor periods, the fair value of the stock price is the closing price for the Company's common stock as reported on the NYSE American.

Expected Life. The expected life is calculated using the simplified method as the Company does not have sufficient historical information to provide a basis for the estimate. The simplified method is based on the average of the vesting tranches and the contractual life of each grant.

Expected Volatility. The expected volatility is estimated based on a study of selected publicly traded peer companies as the Company does not have sufficient trading history for its common stock. The Company selected the peer group based on similarities in industry, stage of development, size and financial leverage with the Company's principal business operations. For each grant, the Company measured historical volatility over a period equivalent to the expected life.

*Risk-free Interest Rate.* The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues whose term is similar in duration to the expected life of the respective stock option.

Expected Dividend Yield. The Company has not paid and does not anticipate paying any dividends on its common stock in the foreseeable future. Accordingly, the Company has estimated the dividend yield to be zero.

# **Note 11. Subsequent Events**

The Company has evaluated subsequent events for recognition and remeasurement purposes as of and for the twelve months ended December 31, 2024. After review and evaluation, management has concluded that there were no material subsequent events as of the date that the financial statements were available to be issued, except as discussed below.

# Public Offering

On January 6, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Aegis Capital Corp. ("Aegis" or the "Underwriter") pursuant to which the Company agreed to sell and issue, in an underwritten public offering (the "Offering") 555,571 Common Units, each consisting of (i) one (1) share of Common Stock, (ii) one (1) Series A Registered Common Warrant to purchase one (1) share of Common Stock per warrant at an exercise price of \$45.00 (the "Series A Warrants") and (iii) one (1) Series B Registered Common Warrant to purchase one (1) share of Common Stock per warrant at an exercise price of \$45.00 (the "Series B Warrants" and together with the Series A Warrants, the "Warrants"). Additionally, the Company granted Aegis a 45-day option to purchase additional shares of Common Stock and/or Warrants of (i) up to 15.0% of the number of shares of Common Stock sold in the offering, (ii) up to 15.0% of the number of Series B Warrants sold in the offering. The purchase price per additional share of Common Stock is equal to the public offering price of one Common Unit (less \$0.01 allocated to each full Warrant), less the underwriting discount. The purchase price per additional Warrant is \$0.01. On January 7, 2025, Aegis exercised its over-allotment option with respect to 83,334 Series A Warrants and 83,334 Series B Warrants.

The closing of the Offering occurred on January 7, 2025. The Company received net proceeds of approximately \$18.3 million from the Offering, after deducting the offering expenses payable by the Company, including the Underwriter's fees and expenses.

Special Meeting of Shareholders

On February 24, 2025, the following proposals were approved at a special meeting of shareholders:

- An amendment to the Company's certificate of incorporation to increase the number of authorized shares of our common stock, par value \$0.0001 (the "Common Stock") from 500,000,000 to 1,040,000,000;
- Discretionary authority granted to the Company's board of directors to (i) amend the Company's certificate of incorporation to combine outstanding shares of the Company's common stock into a lesser number of outstanding shares at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-one hundred fifty (1-for-150), with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect the reverse stock split, if at all, within one year of the date the proposal is approved by stockholders;
- Authorized shares of common stock underlying the warrants and certain provisions of the warrants issued in connection with a public offering that was consummated on January 7, 2025.

Reverse Stock Split

On February 24, 2025, following the Special Meeting of Shareholders, the Board approved the filing of a Certificate of Amendment to the Certificate of Incorporation (the "Charter Amendment") to effect a reverse stock split at a split ratio of 1-for-72 (the "Reverse Stock Split").

As a result of the Reverse Stock Split, each 72 pre-split shares of Common Stock outstanding will automatically combine into one new share of Common Stock without any action on the part of the holders. The Reverse Stock Split will affect all of the Company's stockholders uniformly and will not affect any stockholder's percentage ownership interests in the Company. No fractional shares will be issued in connection with the Reverse Stock Split. In lieu of fractional shares, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the reclassification and combination following the effective time of the Reverse Stock Split (after taking into account all fractional shares of Common Stock otherwise issuable to such holder) shall instead receive a number of shares rounded up to the nearest whole share. Proportional adjustments will be made to the number of shares of Common Stock issuable upon exercise or conversion of the Company's outstanding equity awards and warrants, as well as the applicable exercise price, except in cases where the applicable agreement provides otherwise. On February 26, 2025, the effective date of the Reverse Stock Split, the number of outstanding shares of Common Stock was reduced from approximately 79.9 million shares to approximately 1.1 million shares (subject to rounding of fractional shares, which will be rounded up to the nearest whole share). The capital stock accounts, all share data and earnings (loss) per share, restricted stock units and stock options and corresponding exercise price give effect to the reverse stock split, applied retrospectively, to all periods presented for Successor and on-the-line periods. However, share amounts and per share data for the Predecessor have not been adjusted to reflect our 1-for-72 reverse stock split because the capital structure of Predecessor is not comparable to the Successor.

## Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A. Controls and Procedures

### **Evaluation of Disclosure Controls and Procedures**

Disclosure controls and procedures are designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specific in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Per Rules 13a-15(e) and 15d-15(e), the term disclosure controls and procedures means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act (15 U.S.C. 78a et seq.) is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our Chief Executive Officer ("certifying officer"), in his role as Principal Executive and Financial Officer, has conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of December 31, 2024. Our certifying officer concluded that, as a result of the material weaknesses in internal control over financial reporting as described below, our disclosure controls and procedures were not effective as of December 31, 2024.

# Management's Annual Report on Internal Control over Financing Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Principal Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024 as a result of the material weaknesses in internal control over financial reporting as described below.

Our certifying officer concluded that the Company did not have an effective risk assessment over complex transactions due to the lack of sufficient and qualified resources. This also led to a deficiency in the design and implementation of controls over in-process research and development and valuation of financial instruments. The material weaknesses resulted in a restatement of our financial statements as described in the Explanatory Note to the Quarterly Report Form 10Q/A for the quarter ended September 30, 2023 filed on March 29, 2024 and the Explanatory Note to the Annual Report Form 10K/A for the year ended December 31, 2023 filed on May 14, 2024. We also identified a material weakness related to the lack of segregation of duties in the financial reporting process due to the lack of sufficient resources. Furthermore, the control deficiencies described above created a reasonable possibility that a material misstatement to the consolidated financial statements would not be prevented or detected on a timely basis.

Additionally, as previously disclosed, on July 21, 2023, AEON completed a Merger with Old AEON and Merger Sub, pursuant to which Merger Sub merged with and into Old AEON, with Old AEON surviving the merger as a wholly-owned subsidiary of AEON. Prior to the Merger, Priveterra was a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization, or other similar business combination with one or more target businesses. As a result, previously existing internal controls are no longer applicable or comprehensive enough as of the assessment date considering the Company's operations prior to the Merger were insignificant compared to those of the Post-Combination Company. The design and implementation of internal controls over financial reporting for the Post-Combination Company has required and will continue to require significant time and resources from management and other personnel.

Based on our assessment, we have continued to identify a material weakness in connection with Priveterra's internal controls around the interpretation and accounting for extinguishment of a significant contingent obligation as of December 31, 2022 that were not effectively designed or maintained.

# Remediation Status of Material Weaknesses in Internal Control over Financial Reporting

We plan to enhance our processes by designing and implementing controls to review the results of valuations and estimates, including the completeness and accuracy of relevant data elements included in the valuation or estimate. We also plan to engage additional qualified resources and/or hire additional staff to ensure these incremental controls are properly implemented and to ensure proper segregation of duties around the review of manual journal entries.

Management continues to be actively engaged to take steps to remediate the material weaknesses, including enhanced processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand the nuances of the complex accounting standards that apply to our consolidated financial statements, providing enhanced access to accounting literature, research materials and documents, and increased communication among our personnel and third-party professionals with whom we consult regarding complex accounting applications.

# **Changes in Internal Control over Financial Reporting**

Management has continued to take action to remediate the material weaknesses during the year ended December 31, 2024. However, the material weaknesses will not be considered remediated until management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

Other than described above, there has not been any changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the quarter to which this Report relates that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

# **Inherent Limitations of Internal Controls**

Our management, including our chief executive officer and chief financial officer, or persons performing similar functions, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud due to inherent limitations of internal controls. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

### Item 9B. Other Information

During the fiscal year ended December 31, 2024, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" (in each case, as defined in Item 408 of Regulation S-K).

# Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

#### PART III

# Item 10. Directors, Executive Officers and Corporate Governance

The information regarding director, officers and corporate governance is incorporated by reference to the information under the caption "Corporate Governance" that will be included in the AEON Biopharma, Inc. Proxy Statement for our 2025 Annual Meeting of Shareholders.

# **Item 11. Executive Compensation**

The information regarding executive compensation is incorporated by reference to the information under the caption "Executive and Director Compensation" that will be included in the AEON Biopharma, Inc. Proxy Statement for our 2025 Annual Meeting of Shareholders.

# Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information regarding beneficial ownership and related stockholder matters are incorporated by reference to the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" that will be included in the AEON Biopharma, Inc. Proxy Statement for our 2025 Annual Meeting of Shareholders.

# Item 13. Certain Relationships and Related Transactions and Director Independence

The information regarding related party transactions and director independence are incorporated by reference to the information under the captions "Certain Relationships and Related Person Transactions" and "Director Independence" that will be included in the AEON Biopharma, Inc. Proxy Statement for our 2025 Annual Meeting of Shareholders.

# **Item 14. Principal Accountant Fees and Services**

The information regarding principal accountant fees and services is incorporated by reference to the information under the caption "Audit, Audit-Related, Tax and All Other Fees" that will be included in the AEON Biopharma, Inc. Proxy Statement for our 2025 Annual Meeting of Shareholders.

### **PART IV**

# Item 15. Exhibits and Financial Statement Schedules

- (a) Documents filed as part of this Form 10-K.
  - (1) Financial Statements: See Item 8, "Financial Statements and Supplementary Data" for a list of financial statements.
  - (2) Financial Statement Schedules: All schedules omitted are inapplicable or the information required is shown in the consolidated financial statements or notes thereto.
  - (3) Exhibits Required by Item 601 of Regulation S-K: The information called for by this paragraph is set form in Item 15(b) below.
- (b) Exhibits: See Exhibit Index

# **EXHIBIT INDEX**

Vo.	Description
2.1*	Business Combination Agreement, dated as of December 12, 2022, by and among Priveterra Acquisition Corp.,
	Priveterra Merger Sub, Inc. and AEON Biopharma, Inc. (incorporated by reference to Exhibit 2.1 to the Form 8-K filed
	by Priveterra Acquisition Corp. with the SEC on December 13, 2022)
2.1(a)*	Amendment No. 1 to Business Combination Agreement, dated as of April 27, 2023, by and among Priveterra
	Acquisition Corp., AEON Biopharma, Inc. and Priveterra Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to
_	the Form 8-K filed by Priveterra Acquisition Corp. with the SEC on May 1, 2023)
.1	Third Amended and Restated Certificate of Incorporation of AEON Biopharma, Inc. (incorporated by reference to
	Exhibit 3.1 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
.2	Amended and Restated Bylaws of AEON Biopharma, Inc. (incorporated by reference to Exhibit 3.2 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
.1	Warrant Agreement between Priveterra Acquisition Corp. and Continental Stock Transfer & Trust Company, dated as or
	February 8, 2021 (incorporated by reference to Exhibit 4.1 to the Form 10-K filed by Priveterra Acquisition Corp. with the SEC on March 28, 2022)
.2	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.2 to the Form 10-K filed by Priveterra Acquisition
.2	Corp. with the SEC on March 29, 2024)
.3	Senior Secured Convertible Note, by and among AEON Biopharma, Inc., Daewoong Pharmaceutical Co., LTD. and
	AEON Biopharma Sub, Inc. (incorporated by reference to Exhibit 4.1 to the Form 8-K filed by the Company with the
	SEC on March 28, 2024)
.4	Senior Secured Convertible Note, by and among AEON Biopharma, Inc., Daewoong Pharmaceutical Co., LTD. and
	AEON Biopharma Sub, Inc. (incorporated by reference to Exhibit 4.1 to the Form 8-K filed by the Company with the
	SEC on April 17, 2024)
5	Description of AEON Biopharma Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of
	1934 (incorporated by reference to Exhibit 4.5 to the Form 10-K filed by the Company with the SEC on August 12,
	2024)
).1+	AEON Biopharma, Inc. Amended and Restated 2019 Incentive Award Plan (incorporated by reference to Exhibit 10.1 to
	the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.1(a) +	Form of Stock Option Agreement under AEON Biopharma, Inc. Amended and Restated 2019 Incentive Award Plan
	(incorporated by reference to Exhibit 10.2 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.1(b) +	Form of Restricted Stock Unit Agreement under AEON Biopharma, Inc. Amended and Restated 2019 Incentive Award
	Plan (incorporated by reference to Exhibit 10.3 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.1(c) +	Form of Restricted Stock Unit Agreement under AEON Biopharma, Inc. Amended and Restated 2019 Incentive Award
	Plan (409A Deferred Compensation) (incorporated by reference to Exhibit 10.4 to the Form 8-K filed by the Company
	with the SEC on July 27, 2023)
0.2+	AEON Biopharma, Inc. 2023 Incentive Award Plan (incorporated by reference to Exhibit 10.5 to the Form 8-K filed by
0.0().	the Company with the SEC on July 27, 2023)
0.2(a)+	Form of Stock Option Agreement under AEON Biopharma, Inc. 2023 Incentive Award Plan (incorporated by reference
0.0(1):	to Exhibit 10.6 to the Form S-4/A filed by Priveterra Acquisition Corp. with the SEC on May 1, 2023)
0.2(b)+	Form of Restricted Stock Unit Agreement under AEON Biopharma, Inc. 2023 Incentive Award Plan (incorporated by
0.21	reference to Exhibit 10.7 to the Form S-4/A filed by Priveterra Acquisition Corp. with the SEC on May 1, 2023)
0.3+	AEON Biopharma, Inc. 2023 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.9 to the
0.4+	Form S-1/A filed by the Company with the SEC on April 2, 2024) AEON Biopharma, Inc. Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.6 to
U. <del>4</del> ⊤	the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.5+	Amended and Restated Employment Agreement, by and between AEON Biopharma, Inc. and Marc Forth (incorporated
U.J F	by reference to Exhibit 10.11 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.6+	Employment Agreement, by and between AEON Biopharma, Inc. and Chad Oh (incorporated by reference to Exhibit
0.01	10.12 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.7+	Employment Agreement, by and between AEON Biopharma, Inc. and Alex Wilson (incorporated by reference to Exhibit
0./ 1	10.13 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
0.8+	Consulting Agreement, by and between AEON Biopharma, Inc. and Eric Carter, M.D., dated January 30, 2020, and
0.01	amended on January 30 2020 and September 30, 2020 (incorporated by reference to Exhibit 10.11 to the Annual Report

- Amended and Restated Registration Rights Agreement, dated as of July 21, 2023, by and between AEON Biopharma, Inc. and the stockholders party thereto (incorporated by reference to Exhibit 10.20 to the Form 8-K filed by the Company with the SEC on July 27, 2023)
- Termination Agreement, dated March 18, 2024, by and between AEON Biopharma, Inc. and ACM ARRT J LLC (incorporated by reference to Exhibit 10.5 to the Form 8-K filed by the Company with the SEC on March 19, 2024)
- Termination Agreement, dated March 18, 2024, by and between AEON Biopharma, Inc. and Polar Multi-Strategy Fund (incorporated by reference to Exhibit 10.6 to the Form 8-K filed by the Company with the SEC on March 19, 2024)
- Subscription Agreement, dated March 19, 2024, by and between AEON Biopharma, Inc., Daewoong Pharmaceutical Co., LTD. and AEON Biopharma Sub, Inc. (incorporated by reference to Exhibit 10.1 to the Form 8-K filed by the Company with the SEC on March 19, 2024)
- Security Agreement, dated March 19, 2024, by and among AEON Biopharma, Inc., Daewoong Pharmaceutical Co., LTD. and AEON Biopharma Sub, Inc. (incorporated by reference to Exhibit 10.2 to the Form 8-K filed by the Company with the SEC on March 19, 2024)
- Guaranty, dated March 19, 2024, by and between Daewoong Pharmaceutical Co., LTD. and AEON Biopharma Sub, Inc. (incorporated by reference to Exhibit 10.3 to the Form 8-K filed by the Company with the SEC on March 19, 2024)
- License and Supply Agreement, dated as of December 20, 2019, by and between Daewoong Pharmaceutical Co., LTD. and AEON Biopharma, Inc. (incorporated by reference to Exhibit 10.15 to the Form S-4 filed by Priveterra Acquisition Corp. with the SEC on December 27, 2022)
- Amendment to License and Supply Agreement, dated as of July 29, 2022, by and between Daewoong Pharmaceutical Co., LTD. and AEON Biopharma, Inc. (incorporated by reference to Exhibit 10.15(a) to the Form S-4 filed by Priveterra Acquisition Corp. with the SEC on December 27, 2022)
- 10.15(b) Second Amendment to the License and Supply Agreement, dated as of January 8, 2023, by and between AEON Biopharma, Inc. and Daewoong Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.17(b) to the Form S-1/A filed by the Company with the SEC on April 2, 2024)
- Third Amendment to License and Supply Agreement, dated April 24, 2023, by and between Daewoong Pharmaceutical Co. (incorporated by reference to Exhibit 10.17(c) to the Form S-1/A filed by the Company with the SEC on April 2, 2024)
- 10.15(d) Fourth Amendment to License and Supply Agreement, dated March 19, 2024, by and between AEON Biopharma, Inc. and Daewoong Pharmaceutical Co., LTD. (incorporated by reference to Exhibit 10.4 to the Form 8-K filed by the Company with the SEC on March 19, 2024)
- Settlement and License Agreement dated as of June 21, 2021, by and between AEON Biopharma, Inc. and Medytox, Inc. (incorporated by reference to Exhibit 10.16 to the Form S-4 filed by Priveterra Acquisition Corp. with the SEC on December 27, 2022)
- 10.16(a) Amendment to Settlement and License Agreement, dated as of May 5, 2022, by and between AEON Biopharma, Inc. and Medytox, Inc. (incorporated by reference to Exhibit 10.16(a) to the Form S-4 filed by Priveterra Acquisition Corp. with the SEC on December 27, 2022)
- 10.17 Sponsor Support Agreement, dated as of December 12, 2022, by and among Priveterra Sponsor, LLC, Priveterra Acquisition Corp., and the other parties thereto (incorporated by reference to Exhibit 10.18 to the Form S-1/A filed by the Company with the SEC on November 24, 2023)
- Amendment No. 1 to Sponsor Support Agreement, dated as of April 27, 2023, by and among Priveterra Sponsor, LLC, Priveterra Acquisition Corp., and the other parties thereto (incorporated by reference to Exhibit 10.17 to the Form S-4/A filed by Priveterra Acquisition Corp. with the SEC on May 1, 2023)
- 19 Insider Trading Policy
- 21.1† List of Subsidiaries of AEON Biopharma, Inc.
- 23.1† Consent of Independent Registered Public Accounting Firm
- 24.1† Power of Attorney (included on signature page)
- 31.1† Certification of Principal Executive and Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1† Certification of Principal Executive Officer and Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 97.1 AEON Biopharma, Inc. Policy for Recovery of Erroneously Awarded Compensation (incorporated by reference to Exhibit 97 to the Annual Report on Form 10-K filed by the Company with the SEC on March 29, 2024)
- 101.INS† XBRL Instance Document the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
- 101.SCH† XBRL Taxonomy Extension Schema Document

101.CAL†	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF†	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB†	XBRL Taxonomy Extension Label Linkbase Document
101.PRE†	XBRL Taxonomy Extension Presentation Linkbase Document
104†	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

<sup>†</sup> Filed herewith.

# Item 16. Form 10-K Summary

None.

<sup>\*</sup> The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

<sup>+</sup> Indicates a management contract or compensatory plan.

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, duly authorized.

Date: March 24, 2025

# AEON BIOPHARMA, INC.

By: /s/ Marc Forth

Name: Marc Forth

Title: President and Chief Executive Officer (Principal Executive and Financial Officer)

# POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Marc Forth as such individual's true and lawful attorney in fact and agent with full power of substitution, for such individual in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K (including post-effective amendments), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney in fact, proxy and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney in fact, proxy and agent, or the individual's substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Marc Forth Marc Forth	President, Chief Executive Officer and Director (Principal Executive and Financial Officer)	March 24, 2025
/s/ Jennifer Sy	Vice President, Corporate Controller	March 24, 2025
Jennifer Sy	(Principal Accounting Officer)	
/s/ Jost Fischer Jost Fischer	Chairman of the Board	March 24, 2025
/s/ Shelley Thunen Shelley Thunen	Director	March 24, 2025
/s/ Robert Palmisano Robert Palmisano	Director	March 24, 2025
/s/ Eric Carter Eric Carter	Director	March 24, 2025
/s/ Shawn Park Shawn Park	Director	March 24, 2025