

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 8, 2024

BridgeBio Pharma, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

3160 Porter Dr., Suite 250
Palo Alto, CA
(Address of Principal Executive Offices)

001-38959
(Commission File Number)

84-1850815
(IRS Employer Identification No.)

94304
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 391-9740

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|-------------------|---|
| Common Stock, par value \$0.001 per share | BBIO | The Nasdaq Global Select Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 8.01 Other Events.

On January 8, 2024, BridgeBio Pharma, Inc., or the Company, presented a business update at the 42nd Annual J.P. Morgan Healthcare Conference. A copy of the Company's presentation slides, which has been published on the Company's website, is filed as Exhibit 99.1 to this current report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

| Exhibit | Description |
|---------|--|
| 99.1 | Slides from BridgeBio Pharma, Inc.'s JP Morgan Presentation, dated January 8, 2024 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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 hereunto duly authorized.

BridgeBio Pharma, Inc.

Date: January 8, 2024

By: /s/ Brian C. Stephenson

Brian C. Stephenson
Chief Financial Officer

bridgebio

hope through
rigorous science

JPM
Presentation

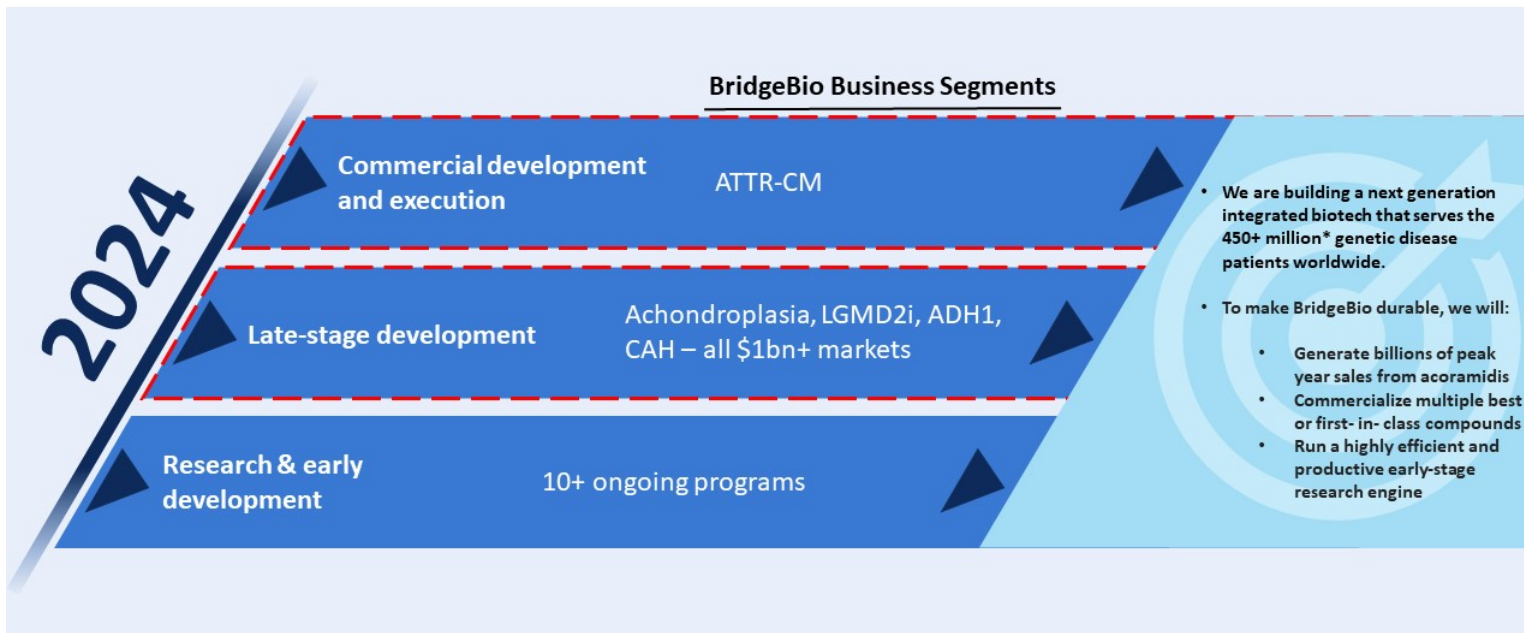
2024



Forward-Looking Statement and Disclaimer

The presentation may contain forward-looking statements. Statements made or presented may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as “believe,” “anticipate,” “plan,” “expect,” “intend,” “will,” “may,” “goal,” “potential,” “should,” “could,” “aim,” “estimate,” “predict,” “continue” and similar expressions or the negative of these terms or other comparable terminology are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. These forward-looking statements, including statements relating to the clinical, therapeutic and market potential of our programs and product candidates, including the timing and success of our clinical development programs, including acoramidis for the treatment of transthyretin amyloidosis, low-dose infigratinib for the treatment of achondroplasia, encaleret for the treatment of ADH1, BBP-418 for the treatment of LGMD2I, and other clinical programs; the progress of our ongoing and planned clinical trials; the availability of data from our clinical trials of our product candidates; the potential benefits of our product candidates; the planned interactions with the FDA or other regulatory agencies, the timing and expectations of any potential regulatory submission and filing; the timing and success of any potential commercial launch of our product candidates, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company, including, without limitation, risks inherent in developing therapeutic products, and those risks and uncertainties described under the heading “Risk Factors” in the Company’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) and in subsequent filings made by the Company with the SEC, which are available on the SEC’s website at www.sec.gov. In light of these risks and uncertainties, many of which are beyond the Company’s control, the events or circumstances referred to in the forward-looking statements, express or implied, may not occur. The actual results may vary from the anticipated results and the variations may be material. You are cautioned not to place undue reliance on these forward-looking statements, which speak to the Company’s current beliefs and expectations only as of the date of the presentation. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements made or presented at the presentation in the event of new information, future developments or otherwise. No representation is made as to the safety or effectiveness of the product candidates for the therapeutic use for which such product candidates are being studied. Certain information communicated at the presentation may relate to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of the presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, certain information to be communicated at the presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, such research has not been verified by any independent source.

Such information is provided as of the date of the presentation and is subject to change without notice. The Company has not verified, and will not verify, any part of this presentation, and the Company makes no representation or warranty, express or implied, as to the accuracy or completeness of the information to be communicated at the presentation or as to the existence, substance or materiality of any information omitted from the presentation at the presentation. The Company disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this document or the related presentation and such liability is expressly disclaimed.



*<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7229282/#bib32>

Where we play: genetic medicine, where it is still Day 1

Massive opportunity to help

- 8,000+ genetic diseases, most without a therapy
- Higher probability of technical success versus other areas
- 100s of actionable opportunities to create first- or best-in-class drugs

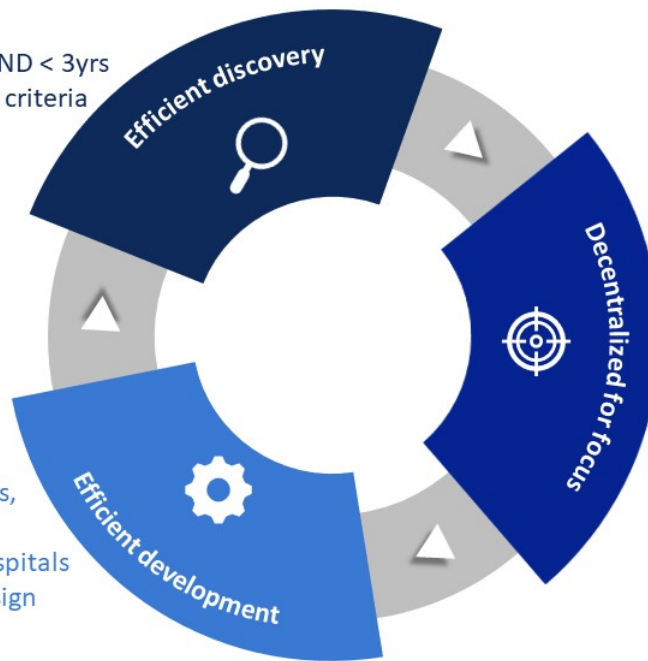


Profound advances in science and medicine

- More information – UKB 500K whole genomes. The complete human reference genome
- More insight on how to go from genetic signal to function
 - Alpha Missense
- More established tools to target diseases at their source

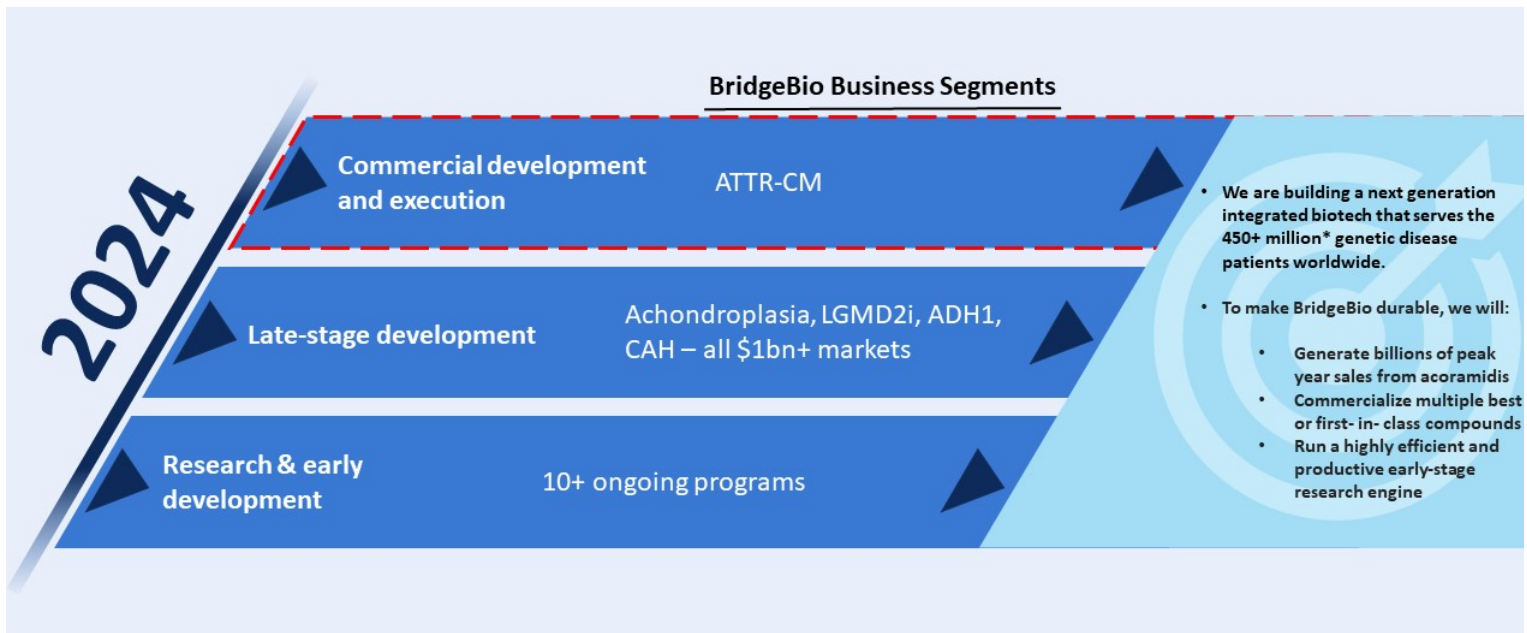
How we play: our R&D engine is purpose-built for genetic medicine

- INDs under \$10m
- Time from start to IND < 3yrs
- Fast-to-fail decision criteria



- Experience across 20+ trials, 25+ countries, 500+ sites including key children's hospitals
- Deep regulatory & trial design expertise

- Incented teams on only their project
- Central resources to variabilize fixed cost



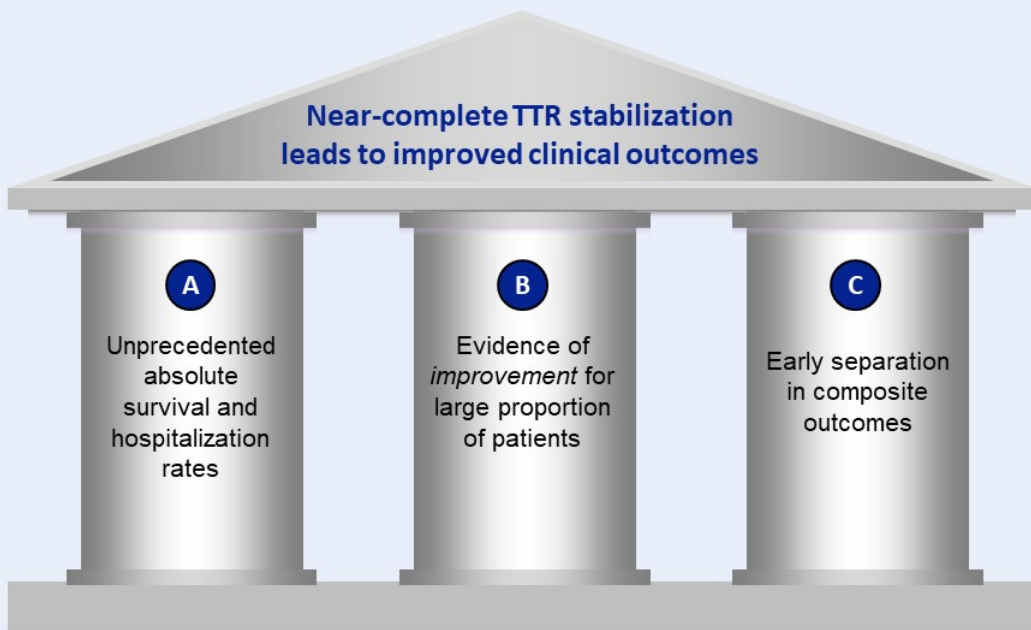
*<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7229282/#bib32>

Learnings across ATTR-CM since JP Morgan 2023

- **Acoramidis provides unprecedented absolute survival and hospitalization rates**
 - As a highly potent next generation stabilizer, acoramidis demonstrated absolute survival and hospitalization rates approaching age-matched general population^{1,2,3}
 - Acoramidis demonstrated separation at 3-months on ACM+CVH, the earliest known separation to date⁴
 - Stabilization levels achieved with acoramidis statistically correlate with downstream mortality at unprecedented levels⁵
- **Dramatic clinical improvements, independent of novel therapies**
 - Clinical context has dramatically improved for ATTR-CM patients
 - Placebo arm of ATTRibute-CM outperformed active tafamidis arm of ATTR-ACT⁶
- **ATTR-CM market is durable and growing**
 - Continued increase in diagnosis rates for ATTR-CM
 - The market is growing at approximately 15% Q on Q⁷
 - EU Opposition Division heard arguments regarding the validity of tafamidis claims in the polymorph patent and agreed with Pfizer, upholding the novelty and inventiveness claims, setting the expectation that Vyndaqel will maintain market exclusivity through Aug. 2035 in EU⁸
- **Increased awareness around identifying progressors on existing treatment**
 - Significant remaining unmet need in ATTR-CM despite current on-market therapies
 - Ability to identify "non-responders", those progressing on existing treatment, via NT-proBNP is ever improving

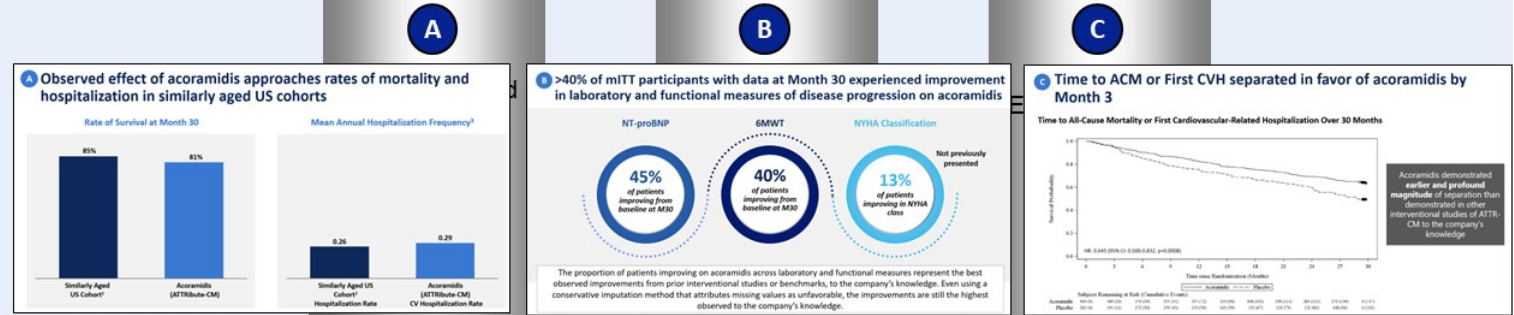
¹ssa.gov. ²US Department of Health & Human Services 2018. ³Natural history reflects US Medicare non-neonatal, non-maternal inpatient stays. ATTRibute-CM data reflect cardiovascular-related hospitalizations. ⁴ATTRibute-CM data, Kaplan-Meier of Composite ACM/CVH. ⁵Preliminary analyses (modeled data) from ATTRibute-CM. Comprehensive analysis to come in 2024. ⁶Masri et al., HFSA 2023 "A Multicenter Study Of Real-world Outcomes Of Tafamidis In Transthyretin Amyloid Cardiomyopathy". Note: Direct cross-study comparisons may suggest misleading similarities or differences. ⁷Corporate SEC Filings. ⁸European Patent Office, Opposition Division, File#EP3191461

Patients on acoramidis are surviving more and going to the hospital less

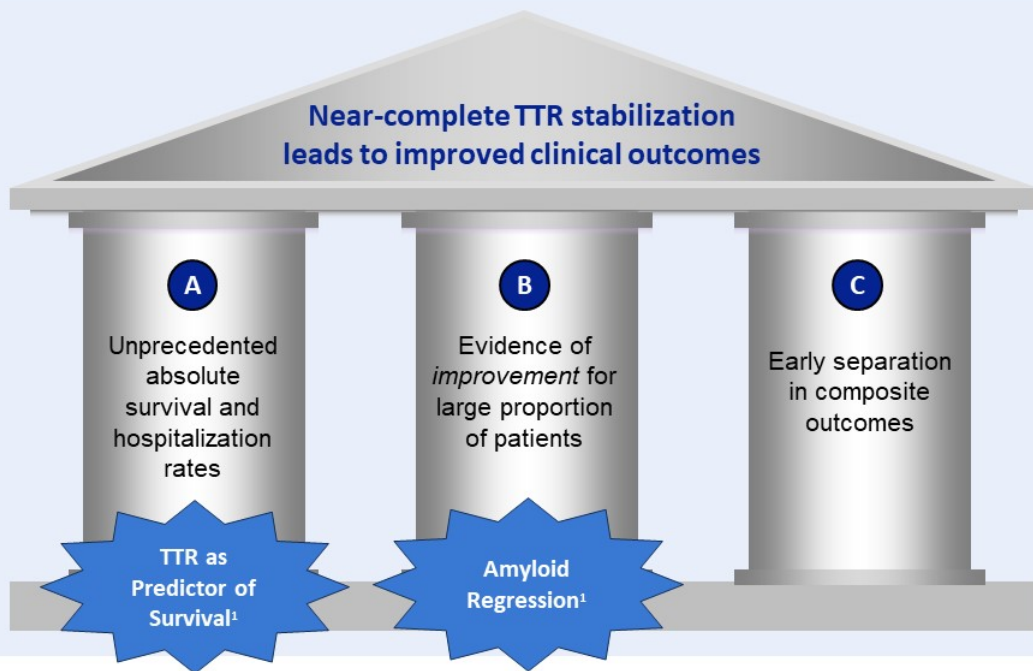


Patients on acoramidis are surviving more and going to the hospital less

Near-complete TTR stabilization leads to improved clinical outcomes

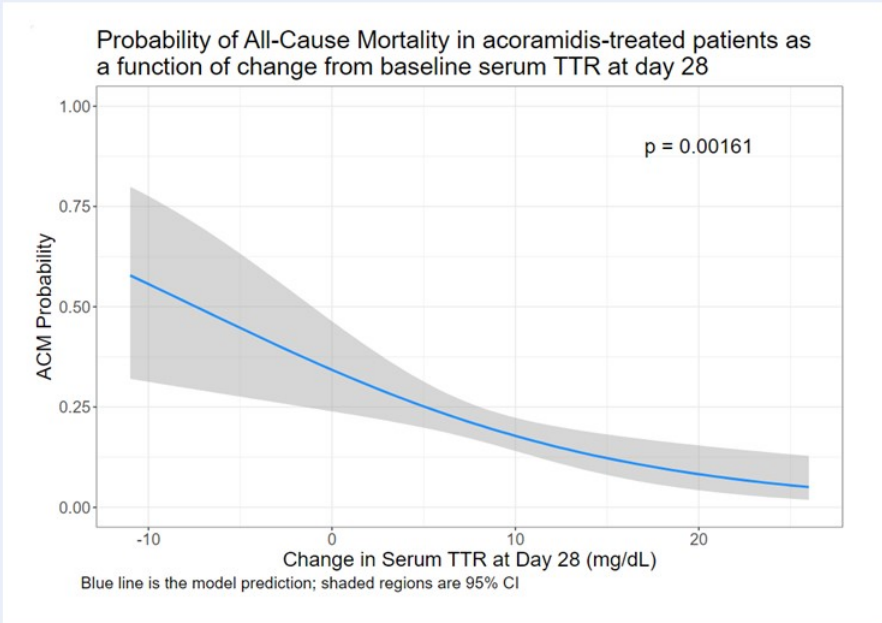


Patients on acoramidis are surviving more and going to the hospital less



¹ Preliminary analyses from ATTRIBUTE-CM. Comprehensive analysis to come in 2024.

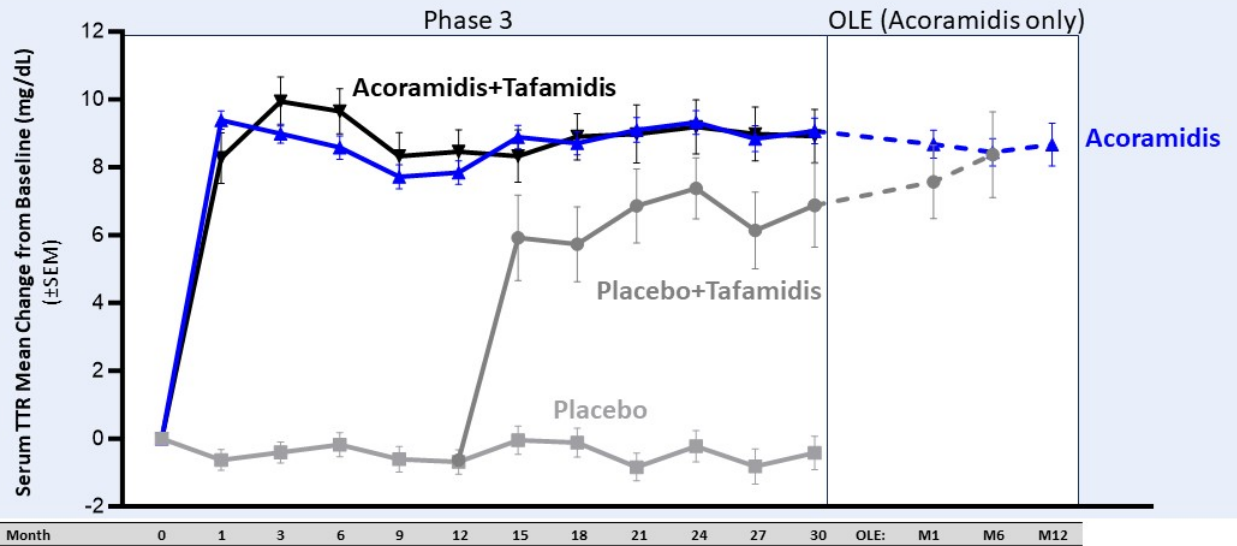
A Data from ATTRIBUTE-CM demonstrate early increase in serum TTR is an independent predictor of improved survival in ATTR-CM



Statistical modeling demonstrates that acoramidis-mediated increase in serum TTR at Day 28 is an independent predictor of survival.

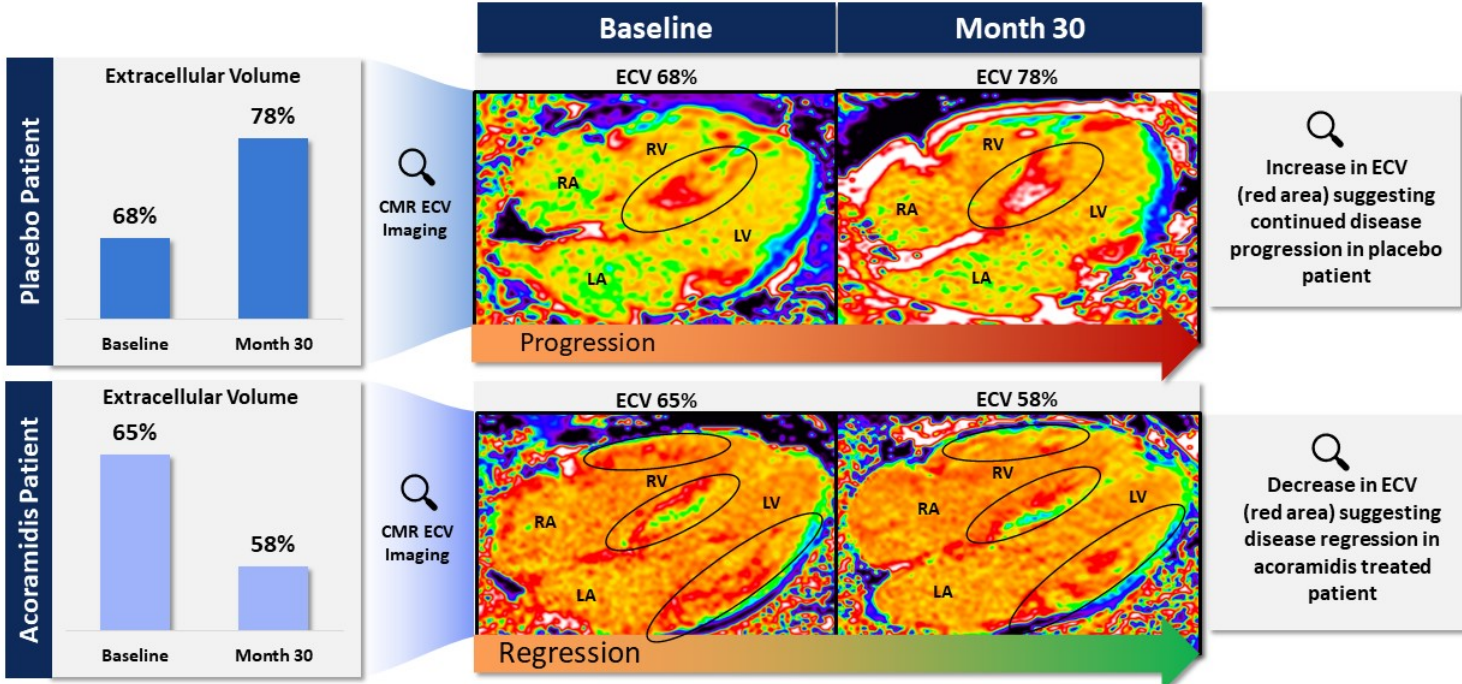
Source: Preliminary analyses (modeled data) from ATTRIBUTE-CM. Comprehensive analysis to come in 2024.

A Higher serum TTR levels may be available to patients who switch from a partial stabilizer to a potent, near-complete stabilizer



Source: Data from ATTRIBUTE-CM and OLE; The sample collection date is at least 14 days after tafamidis start date AND no more than 14 days after the tafamidis end date. OLE results are not shown for Acoramidis+Tafamidis or Placebo groups due to ongoing analyses. In OLE, fraction of Acoramidis only patients continuing was n=222 of the n=234 at month 30, and fraction of Placebo+Tafamidis patients that qualify for OLE, given the above collection dates, was n=21 of n=33

B Preliminary evidence of amyloid regression on CMR imaging demonstrated in ATTRibute-CM imaging sub-study



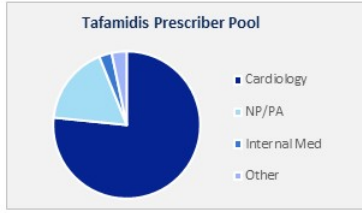
ECV = Extracellular volume, an imaging correlate of amyloid deposition
 Source: Preliminary sample of ATTRibute-CM CMR imaging

*Note: Preliminary analyses / work in progress.
 Comprehensive analysis to come in 2024.*

Precision targeting along with a dedicated and experienced commercial team will lead to an optimal global launch

State of Market

Current tafamidis prescribers are made up mostly of cardiologists



ATTR-CM prescriber market is concentrated

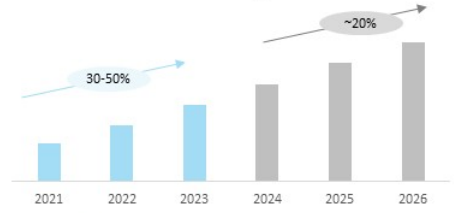


<100 US COEs* hold significant influence with prescribers & communicate overall product value

Future State

Prescriber Pool Evolution

The TAF prescriber base has been growing at 30-50% annually



How we will win / how we will capitalize on this opportunity



We are building a customer facing team that is sized to effectively maximize the opportunity



We have hired a commercial team with strong CV experience and existing relationships with COEs



Undiagnosed patients and unmet need with currently approved medications fuels future market growth

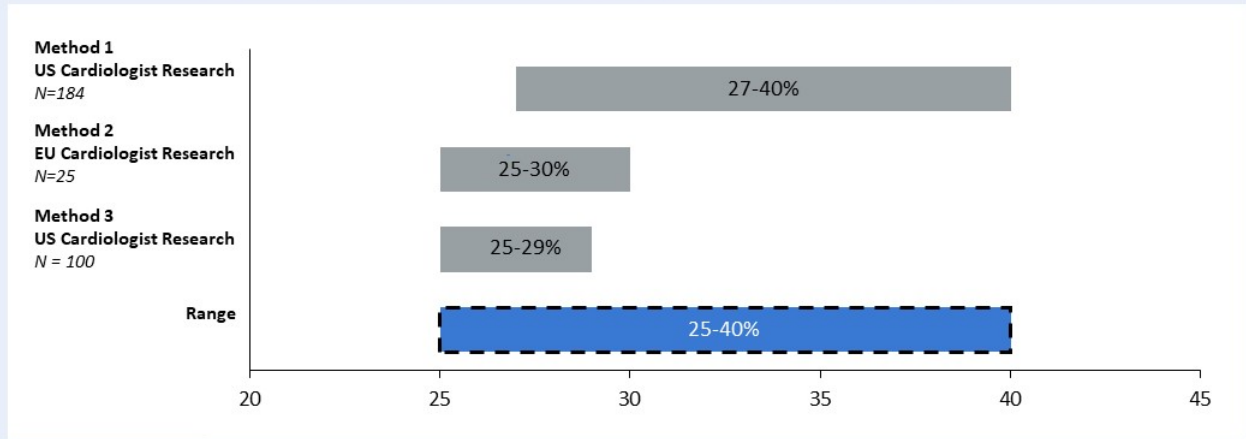
Sources: Data on file
*COEs = Centers of Excellence

Commercial strategy and go-to-market plans in place to establish acoramidis as the backbone of ATTR-CM treatment upon launch in 2024

|  Backbone of Therapy |  Access & Affordability |  Continued Evidence Generation |  Dedicated Focus |
|---|---|--|--|
| <ul style="list-style-type: none">✓ Reinforce benefits of near-complete stabilization✓ Differentiate from partial stabilizers and partial knockdowns | <ul style="list-style-type: none">✓ Ensure broad and sustained access and affordability✓ Design best-in-class patient and provider support | <ul style="list-style-type: none">✓ Additional analyses from ATTRibute-CM✓ Generate new evidence to support diagnosis and treatment | <ul style="list-style-type: none">✓ Dedicated commercial and field-based team with singular focus on serving patients with ATTR-CM |

Independent market research estimates 25-40% market share for acoramidis in a future 4-product market

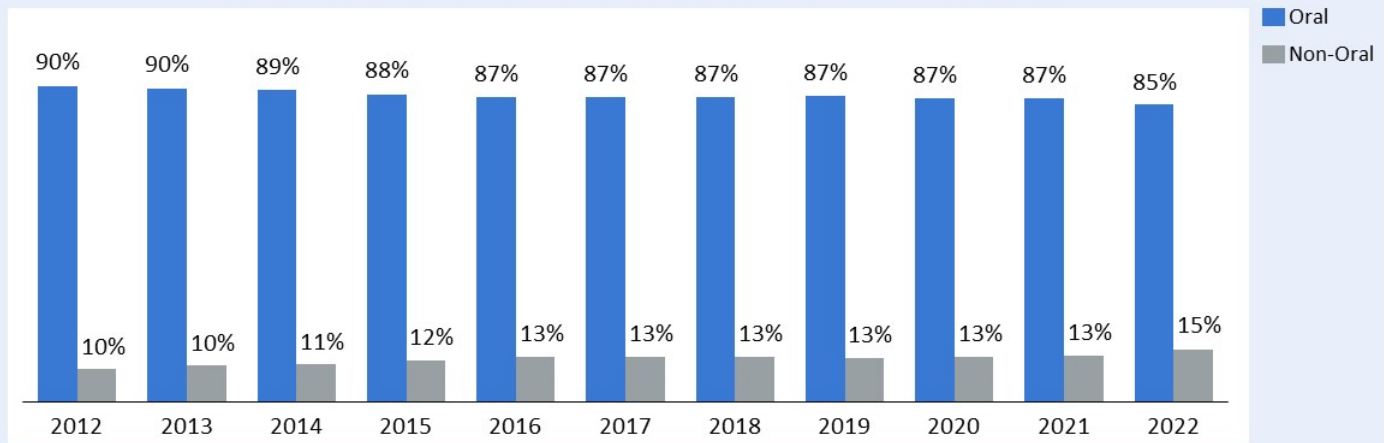
Acoramidis Estimated Market Share as % of Future 4-Product Market



Acoramidis is poised to command significant market share regardless of potential positive knockdown data in 2024.

Cardiovascular markets are dominated by orally administered products

Percentage of cardiovascular sales by route of administration (%)



With oral products dominating 85% of cardiovascular sales in 2022, cardiologists are best educated and equipped to administer oral therapeutics

Acoramidis go-to-market strategy in place ahead of anticipated 2024 launch with robust lifecycle plans underway



Detailed Results from ATTRIBUTE-CM

European Society of Cardiology August 2023
American Heart Association November 2023



Submit New Drug Application (NDA) with FDA

November 2023



Submit additional regulatory filings (EMA & others)

2024



Execute lifecycle management

Initiate primary prevention study (ACT-EARLY) and QD Formulation
2024



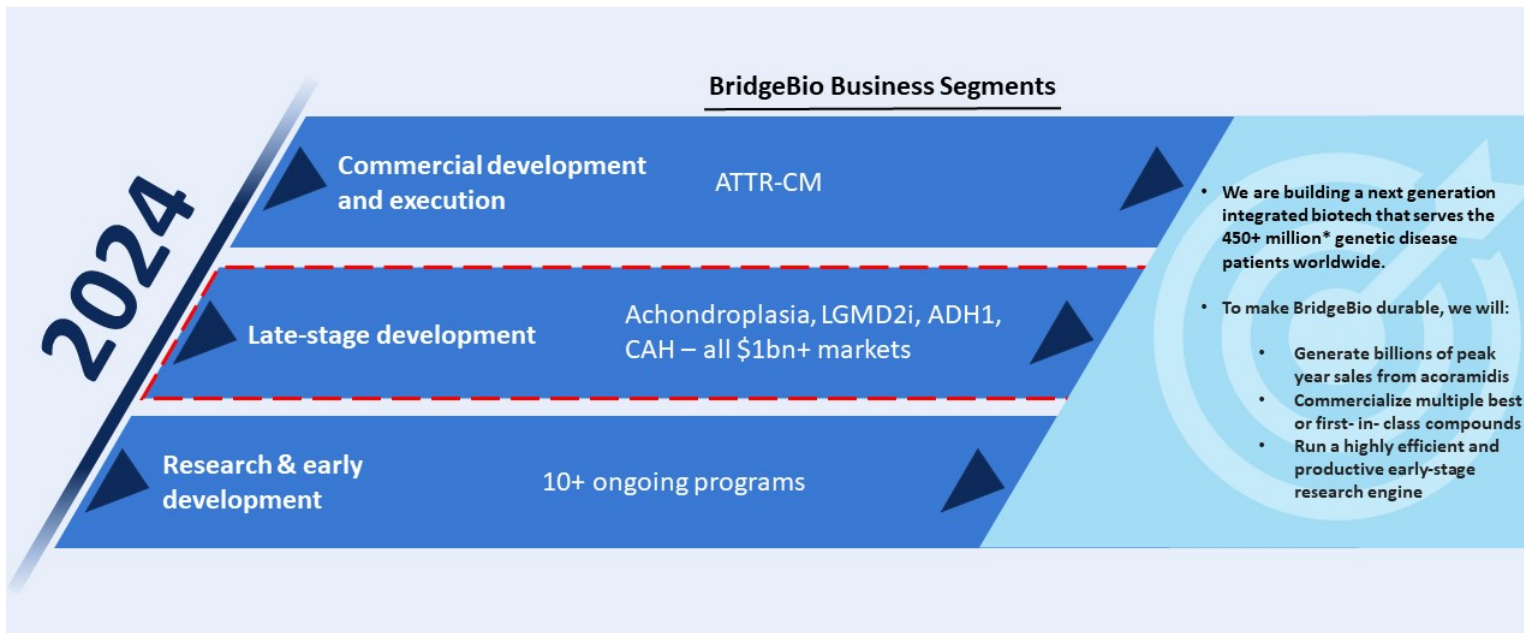
Additional Clinical Data from ATTRIBUTE-CM

Future medical meetings



Anticipated FDA Approval and Commercial Launch

2H 2024



*<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7229282/#bib32>

Low-dose oral FGFR inhibitor (infigratinib) for achondroplasia

Genetic Driver
FGFR3 gain-of-function

Design Principles
Best-in-class (oral, potential greater efficacy, no hypotensive or injection-site reactions)

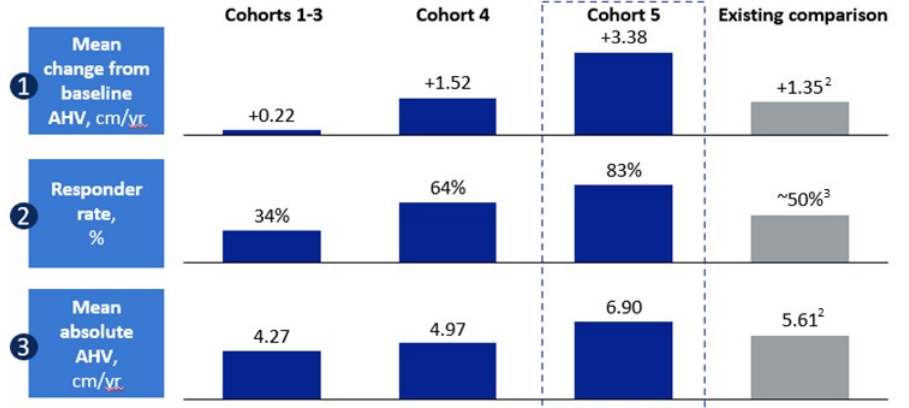
Stage
Phase 3

Total addressable market
\$5Bn

Notes on status

- Achon Ph3 FPI achieved
- Robust enrollment (ahead of timelines) with LPI expected in 1H24¹ and study completion in 2025
- Hypochon. clinical program to initiate in 2024

Data from Cohort 5 of Phase 2 study of infigratinib presented this year



Cohort 5 has demonstrated a well-tolerated safety profile, with:

- 0 severe adverse events
- 0 adverse events assessed as drug-related
- 0 discontinuations due to adverse events
- No accelerated advancement of bone age or worsening of body proportions

¹PROPEL observational lead in study; ²Savarirayan 2020; ³FDA Summary Basis of Approval (imputed from individual waterfall charts)

BBP-418 for Limb-Girdle Muscular Dystrophy Type 21

Long-term data from ongoing Phase 2 study presented at major muscle meetings in 2023¹

Genetic Driver

FKRP partial loss-of-function mutation

Stage

Phase 3

Total addressable market

\$1Bn+

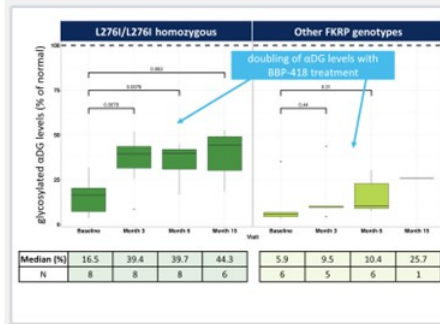
Design principles

First-in-class disease modifying treatment

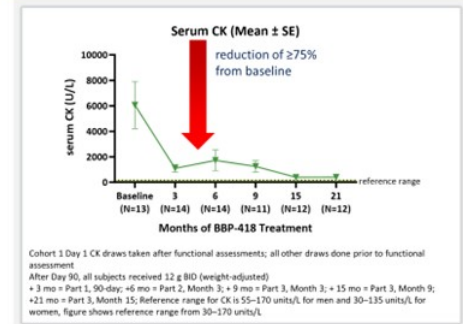
Key next steps

- Phase 3 is enrolling rapidly (ahead of projections)
- Completion of enrollment expected 1H24 for interim analysis in 1H25

Increase in glycosylated αDG post treatment with BBP-418 (median ± 95% CI)



Reduction in mean serum creatine kinase (CK) post treatment with BBP-418



The Phase 3 interim analysis endpoint is change from baseline in glycosylated αDG levels vs. placebo.

Key secondary endpoints include change from baseline in forced vital capacity (FVC) and 100-meter timed test (100mTT).

¹World Muscle Society presentation, October 2023

Encaleret for autosomal dominant hypocalcemia type 1 (ADH1)

Genetic Driver

Gain-of-function variants in the calcium sensing receptor

Stage

Phase 3

Total addressable market

\$1Bn+

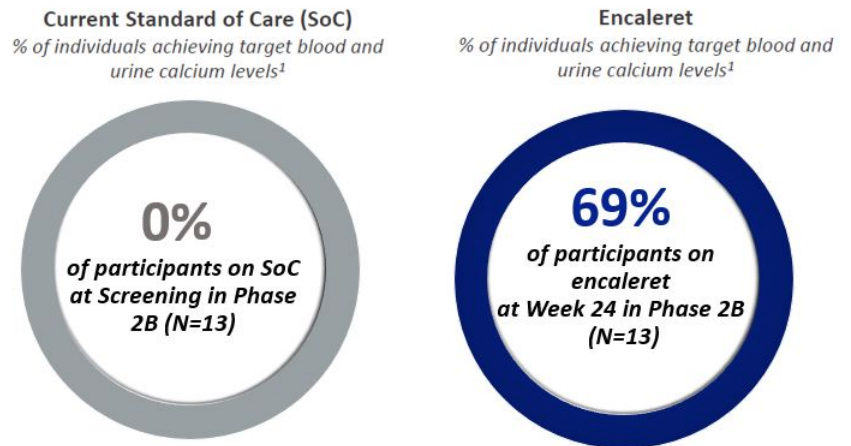
Design principles

First-in-class disease-modifying treatment

Key next steps

- Enrollment behind schedule owing to slow start-up at key academic investigational sites, but now progressing strongly
- Phase 3 readout expected early-2025

Encaleret has the potential to restore physiologic mineral homeostasis in patients with ADH1



Phase 2B results demonstrated rapid and sustained normalization of serum calcium, urine calcium, and serum PTH in response to encaleret therapy. No serious adverse events were reported with encaleret.²

¹As specified by the primary endpoint of the CALIBRATE Phase 3 Study. ²Gafni R.I., NEJM, 2023, 389;13 (1245-47).

BBP-631 for congenital adrenal hyperplasia (CAH)

Loss of 21-hydroxylase in CAH causes loss of cortisol, and shunting of 17OHP into androgens

Genetic Driver

Loss of 21-hydroxylase

Design Principle

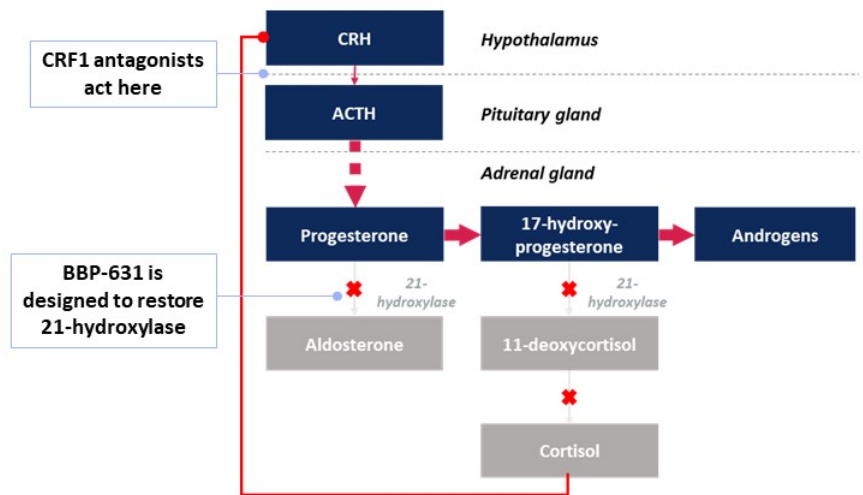
Best-in-class efficacy (upstream and downstream effects)

Stage

Phase 2

Total addressable market

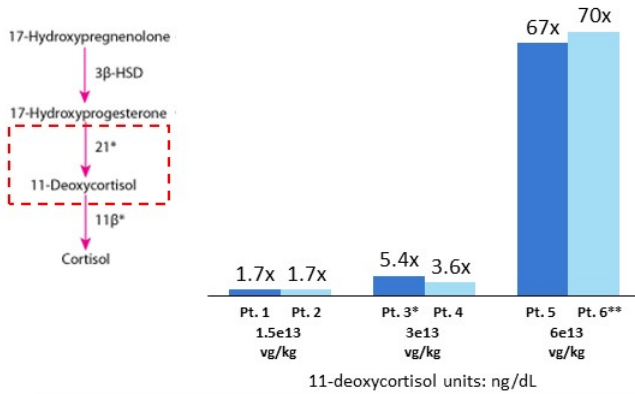
\$2Bn+



Early data show that BBP-631 is the first therapeutic option enabling classic CAH patients to increase endogenous cortisol production; more follow-up is needed

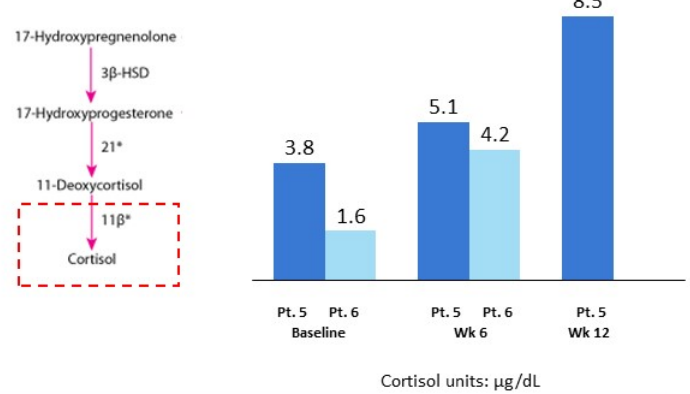
Transgene is active: We are seeing consistent, dose-dependent increases in 11-deoxycortisol...

Fold increase in 11-deoxycortisol from baseline to Wk 12



...Which is translating to early signs of cortisol production for both participants at 6e13 vg/kg

In-clinic cortisol levels measured post-ACTH stim



Given the steep dose response seen to date and our bar for transformative data, we have commenced dosing Cohort 4 (1.2e14 vg/kg), with initial data available in Q3 2024

*Wk 12 not available; Wk 18 measurement used instead

** Pt. 6 only has 6 weeks of in-clinic measurement data available to date

2024 at a high level



Launch Acoramidis: Establish acoramidis as the backbone of therapy in ATTR-CM



Fully enroll our ongoing Phase 3 trials, and readout Phase 2 in CAH: Complete enrollment for achondroplasia, ADH1, LGMD2I, and make a go/no-go Phase 2 decision on our CAH program



Establish a strong financial position: \$560mn of cash and equity investments¹ with expected strategic optionality afforded by our diversified portfolio and large late-stage assets

¹As of last earnings report 11/2/2023, BridgeBio Ended the third quarter with \$522 million in cash, cash equivalents, and short-term restricted cash, and \$38 million of investments in equity securities