

**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): May 4, 2023

BridgeBio Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38959
(Commission
File Number)

84-1850815
(IRS Employer
Identification No.)

3160 Porter Dr., Suite 250
Palo Alto, CA
(Address of principal executive offices)

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 (see General Instruction A.2. below):

- 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 2.02. Results of Operations and Financial Condition.

On May 4, 2023, BridgeBio Pharma, Inc. reported recent business updates and its financial results for the first quarter ended March 31, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

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

Exhibit Number	Description
99.1	Press Release dated May 4, 2023, furnished herewith
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.

Date: May 4, 2023

BridgeBio Pharma, Inc.

/s/ Brian C. Stephenson

Brian C. Stephenson
Chief Financial Officer

BridgeBio Pharma Reports First Quarter 2023 Financial Results and Business Update

- Phase 3 ATTRibute-CM registrational trial of acoramidis for transthyretin amyloid cardiomyopathy (ATTR-CM) has now completed last patient last visit and remains on track for topline month 30 registrational data to be announced in late July 2023
- Positive results announced in Cohort 5 of Phase 2 PROPEL 2 trial of low-dose infigratinib in children with achondroplasia, demonstrating mean increase in annualized height velocity (AHV) of 3.03cm/year with no treatment-related adverse events. This data suggests a potential best-in-class efficacy and well-tolerated safety profile for infigratinib, which also has a differentiated convenience profile due to its oral route of administration
- Shared preliminary findings on novel bioassay measuring glycosylated alpha-dystroglycan (αDG) in patients with limb-girdle muscular dystrophy type 2I (LGMD2I) and 15-month results from ongoing Phase 2 study of BBP-418 for LGMD2I; continuing to progress towards 2023 initiation of a global Phase 3 registrational clinical trial of BBP-418 for LGMD2I
- Phase 3 CALIBRATE registrational trial of encalceret in autosomal dominant hypocalcemia type 1 (ADH1) continues to proceed, with topline data expected to be announced in the first half of 2024
- Phase 1/2 trial of BBP-631 for treatment of congenital adrenal hyperplasia (CAH) progressing with a data update planned by the end of 2023
- Three lead KRAS programs are progressing, with an Investigational New Drug (IND) application planned for first-in-class direct KRAS^{G12C} (ON) inhibitor BBO-8520 in second half of 2023
- Closed underwritten public offering with gross proceeds of approximately \$150 million, and ended the quarter with \$467 million in cash, cash equivalents, marketable securities, and restricted cash (current), providing runway into 2H 2024

Palo Alto, CA – May 4, 2023 – BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio or the Company), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, today reported its financial results for the first quarter ended March 31, 2023 and provided an update on the Company's operations.

“We were excited to announce the results from the 5th cohort of our Phase 2 trial of infigratinib for achondroplasia – an oral agent with a well-tolerated safety profile and best-in-class efficacy to date,” said Neil Kumar, Ph.D., founder and CEO of BridgeBio. “We thank the children and physicians who have partnered with us on this study and are eager to take the next steps for this program together. Infigratinib pairs with our ADH1 program, which reads out its Phase 3 next year, to form a high-quality endocrine franchise that we are continuing to build out. With this dataset for achondroplasia in hand, we look forward to July and the next big readout from our pipeline, the 30-month data from our ATTR-CM Phase 3 trial of acoramidis that recently completed last patient last visit. We thank the ATTR-CM patient and physician communities who made this trial possible, and we look forward to sharing the results with you.”

BridgeBio’s key programs:

- **Acoramidis (AG10) – Transthyretin (TTR) stabilizer for transthyretin amyloid cardiomyopathy (ATTR-CM):**
 - The Phase 3 ATTRibute-CM study has completed last patient last visit.
 - The Company expects to announce topline registrational data for the month 30 primary endpoint, a hierarchical composite including all-cause mortality and cardiovascular-related hospitalizations, in late July, 2023.
- **Low-dose infigratinib – FGFR1-3 inhibitor for achondroplasia and hypochondroplasia:**
 - In March 2023, the Company reported data from the fifth dosing cohort of the Phase 2 dose-escalation trial PROPEL 2, demonstrating a mean change from baseline in annualized height velocity (AHV) of +3.03 cm/year for the ten children that have had six-month visits.
 - 80% of the ten children with six-month visits in the fifth cohort were responders, as defined by an increase from baseline AHV of at least 25%.
 - As a result of treatment, the median absolute AHV reached 7.6 cm/yr, which is beyond the 99th percentile of growth for children living with achondroplasia.
 - Combined with the previously reported Cohort 4 change from baseline in AHV value of +1.52 cm/yr, the Cohort 5 data demonstrate a strong dose response for infigratinib.
 - To date, the study has shown a well-tolerated safety profile, with no study drug related treatment emergent adverse events (TEAEs) in Cohort 5. No serious adverse events (SAEs) or discontinuations due to AEs were reported in any cohort.
 - The Company has begun enrolling children in the run-in for a registrational Phase 3 trial.
 - The Company believes infigratinib, if approved, has the potential to capture a significant share of the market based on blinded market research.
- **BBP-418 – Glycosylation substrate for limb-girdle muscular dystrophy type 2I (LGMD2I):**
 - The Company announced development of a validated novel bioassay that directly measures glycosylated α DG, which is central to LGMD2I disease and enables monitoring of responses to disease-modifying therapies in LGMD2I patients.

- The Company also reported positive 15-month results from the ongoing Phase 2 clinical trial in October 2022, showing a doubling of glycosylated α DG in LGMD2I patients treated with BBP-418; a sustained decrease of $\geq 70\%$ in creatine kinase (CK), a marker of muscle breakdown; and improvements in ambulatory and clinical function measures after 15 months of treatment.
- The Company intends to initiate a global Phase 3 registrational trial of BBP-418 for LGMD2I in mid-2023, and has engaged with regulatory authorities to align on a trial design.
- BBP-418 has a potentially-addressable population of 7,000 patients in the United States and European Union.
- There are currently no disease-modifying treatments available for LGMD2I.
- **Encaleret – Calcium-sensing receptor (*CaSR*) inhibitor for autosomal dominant hypocalcemia type 1 (ADH1):**
 - The pivotal Phase 3 CALIBRATE trial of encaleret for ADH1 continues to proceed.
 - Population genetics analyses estimate approximately 25,000 carriers of gain-of-function variants of the CaSR, the underlying cause of ADH1, in the United States and European Union.
 - The Company anticipates sharing topline data from CALIBRATE in the first half of 2024.
 - If approved, encaleret could be the first therapy specifically indicated for the treatment of ADH1.
- **BBP-631 – AAV5 gene therapy candidate for congenital adrenal hyperplasia (CAH):**
 - The Phase 1/2 gene therapy trial of BBP-631 for CAH continued to progress; as of February 1, 2023, BBP-631 has been generally well-tolerated in four patients treated at the first two dose levels.
 - The Company plans to provide a data update by the end of 2023.
 - CAH is one of the most prevalent genetic diseases potentially addressable with adeno-associated virus (AAV) gene therapy, with more than 75,000 cases estimated in the United States and European Union.
- **RAS cancer portfolio:**
 - BridgeBio is continuing to develop the three main programs of its RAS franchise:
 - BBO-8520, an investigational, next-generation small molecule direct KRAS^{G12C}(ON) inhibitor candidate that is designed to directly bind and inhibit KRAS^{G12C} in both its ON (GTP-bound) and OFF (GDP-bound) conformations, which remains on track to file an IND and enter the clinic in the second half of 2023.
 - A PI3K α :RAS breaker program, investigational small molecules that are designed to block Ras-driven PI3K α activation with a novel and potentially broad mechanism of action to target not only PI3K α mutant tumors and RAS mutant tumors, but potentially other tumors driven by RTK activation of RAS signaling. The Company remains on track to select a development candidate in 2023, with IND filing to follow in 2024.

- The Company's pan-KRAS program, which targets multiple KRAS mutants including KRASG12D and KRASG12V, which are present in a large percentage of colorectal, pancreatic, and non-small cell lung cancer tumors. Development candidate selection for this program is planned for late 2023 or early 2024.

Corporate Update:

- **Follow-on offering:**
 - The Company closed an underwritten public offering of shares of its common stock with gross proceeds of approximately \$150 million.

First Quarter 2023 Financial Results:

Cash, Cash Equivalents, Marketable Securities and Restricted Cash (Current)

Cash, cash equivalents, marketable securities and restricted cash (current), totaled \$467.0 million as of March 31, 2023, compared to \$466.2 million as of December 31, 2022. The net increase of \$0.8 million in cash, cash equivalents, marketable securities and restricted cash (current) is primarily attributable to the net proceeds received of \$143.0 million from the follow-on public offering, and proceeds from common stock issuance under ESPP and stock option exercises of \$2.0 million, partially offset by net cash used in operating activities of \$144.3 million.

Operating Costs and Expenses

Operating costs and expenses decreased by \$47.4 million to \$128.0 million for the three months ended March 31, 2023, compared to \$175.4 million for the same period in the prior year. The overall decrease in operating costs and expenses for the first quarter of 2023 compared to the comparative period was mainly due to decreases in research, development and other (R&D) expenses of \$15.5 million resulting from the Company's reprioritization of its R&D programs; selling, general and administrative expenses of \$12.6 million resulting from its company-wide streamlining of costs; and restructuring, impairment and related charges of \$19.3 million since the majority of the restructuring initiatives were initiated in the first quarter of 2022. The effects of the Company's restructuring initiative that was started in the first quarter of 2022 are continuing to be realized due to the Company's reductions in its operating costs and expenses. Restructuring, impairment and related charges for the three months ended March 31, 2023 of \$3.4 million, were primarily comprised of winding down, exit and other related costs. Restructuring, impairment and related charges for the same period in prior year were \$22.7 million, were primarily related to impairments and write-offs of long-lived assets, severance and employee-related costs, and exit and other related costs. The Company continues to evaluate restructuring alternatives to drive operational changes in business processes, efficiencies, and cost savings.

Stock-based compensation expenses included in operating costs and expenses for the first quarter of 2023 were \$23.5 million, of which \$11.8 million is included in research, development and other (R&D) expenses, \$11.7 million is included in selling, general and administrative expenses, and nil is included in restructuring, impairment and related charges. Stock-based compensation expenses included in operating costs and expenses for the first quarter of 2022 were \$24.3 million, of which \$8.6 million is included in research, development and other (R&D) expenses, \$14.6 million is included in selling, general and administrative expenses, and \$1.2 million is included in restructuring, impairment and related charges.

“Strengthening our balance sheet through our recent \$150 million follow-on offering extends our runway into the second half of 2024, and puts us in a strong position to take advantage of our optionality as we head into this summer’s ATTR-CM readout,” said Brian Stephenson, Ph.D., CFA, Chief Financial Officer of BridgeBio. “We will continue to explore ways to extend our runway further through considering potential partnerships and royalty transactions.”

BRIDGEBIO PHARMA, INC.
Condensed Consolidated Statements of Operations
(in thousands, except shares and per share amounts)

	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
Revenue	\$ 1,826	\$ 1,694
Operating costs and expenses:		
Research, development and others	93,512	108,997
Selling, general and administrative	31,108	43,713
Restructuring, impairment and related charges	3,369	22,662
Total operating costs and expenses	<u>127,989</u>	<u>175,372</u>
Loss from operations	(126,163)	(173,678)
Other income (expense), net:		
Interest income	4,153	267
Interest expense	(20,121)	(20,344)
Other expense, net	(601)	(7,575)
Total other income (expense), net	<u>(16,569)</u>	<u>(27,652)</u>
Net loss	(142,732)	(201,330)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	<u>2,576</u>	<u>4,933</u>
Net loss attributable to common stockholders of BridgeBio	<u>\$ (140,156)</u>	<u>\$ (196,397)</u>
Net loss per share, basic and diluted	<u>\$ (0.92)</u>	<u>\$ (1.35)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>152,645,635</u>	<u>145,882,149</u>

	Three Months Ended March 31,	
	2023	2022
	(Unaudited)	
Stock-based Compensation		
Research, development and others	\$ 11,779	\$ 8,557
Selling, general and administrative	11,698	14,552
Restructuring, impairment and related charges	—	1,172
Total stock-based compensation	<u>\$ 23,477</u>	<u>\$ 24,281</u>

BRIDGEBIO PHARMA, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	March 31, 2023 <u>(Unaudited)</u>	December 31, 2022 <u>(1)</u>
Assets		
Cash and cash equivalents and marketable securities	\$ 441,490	\$ 428,269
Investment in equity securities	49,803	43,653
Receivable from licensing and collaboration agreements	10,761	17,079
Restricted cash	25,503	37,930
Prepaid expenses and other current assets	25,145	21,922
Property and equipment, net	13,566	14,569
Operating lease right-of-use assets	10,532	10,678
Intangible assets, net	28,113	28,712
Other assets	20,767	20,224
Total assets	<u>\$ 625,680</u>	<u>\$ 623,036</u>
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Accounts payable	\$ 4,076	\$ 11,558
Accrued and other liabilities	88,846	106,195
Operating lease liabilities	15,578	15,949
2029 Notes	735,463	734,988
2027 Notes	542,065	541,634
Term loans	435,764	430,993
Other long-term liabilities	17,501	26,643
Redeemable convertible noncontrolling interests	(204)	(1,589)
Total BridgeBio stockholders' deficit	(1,225,665)	(1,254,617)
Noncontrolling interests	12,256	11,282
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	<u>\$ 625,680</u>	<u>\$ 623,036</u>

- (1) The condensed consolidated financial statements as of and for the year ended December 31, 2022 are derived from the audited consolidated financial statements as of that date.

BRIDGEBIO PHARMA, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)

	Three Months Ended March 31,	
	2023	2022
Operating activities:		
Net loss	\$(142,732)	\$(201,330)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	21,907	24,122
Depreciation and amortization	1,633	1,884
Noncash lease expense	1,032	1,545
Accrual of payment-in-kind interest on term loan	3,339	—
Loss on deconsolidation of PellePharm	1,241	—
Loss (gain) from investment in equity securities, net	(964)	12,866
Accretion of debt	2,338	2,483
Fair value adjustment of warrants	(111)	852
Loss on sale of certain assets	—	6,261
Impairment of long-lived assets	—	12,653
Gain from recognition of receivable from licensing and collaboration agreement	—	(12,500)
Other noncash adjustments	(203)	604
Changes in operating assets and liabilities:		
Receivable from licensing and collaboration agreements	6,318	10,266
Prepaid expenses and other current assets	(3,542)	(2,657)
Other assets	(483)	7,901
Accounts payable	(3,800)	(1,814)
Accrued compensation and benefits	(18,369)	(16,876)
Accrued research and development liabilities	(2,556)	(818)
Accrued professional services	2,225	(1,374)
Operating lease liabilities	(1,250)	(1,820)
Deferred revenue	(1,748)	—
Other accrued and other long-term liabilities	(8,597)	(2,883)
Net cash used in operating activities	(144,322)	(160,635)
Investing activities:		
Purchases of marketable securities	—	(55,722)
Maturities of marketable securities	18,000	186,695
Purchases of investment in equity securities	(47,474)	(8,162)
Sales of investment in equity securities	42,287	6,671
Decrease in cash and cash equivalents resulting from deconsolidation of PellePharm	(503)	—
Proceeds from sale of certain assets	—	10,000
Purchases of property and equipment	(12)	(859)
Net cash provided by investing activities	12,298	138,623
Financing activities:		
Proceeds from issuance of common stock through Follow-on offering, net	143,016	—
Proceeds from BridgeBio common stock issuances under ESPP	1,809	966
Repurchase of shares to satisfy tax withholding	(512)	(110)
Issuance costs associated with term loan	—	(1,120)
Proceeds from stock option exercises, net of repurchases	193	104
Other financing activities	5,743	—
Net cash provided by (used in) financing activities	150,249	(160)
Net increase (decrease) in cash, cash equivalents and restricted cash	18,225	(22,172)
Cash, cash equivalents and restricted cash at beginning of period	416,884	396,365
Cash, cash equivalents and restricted cash at end of period	<u>\$ 435,109</u>	<u>\$ 374,193</u>

	Three Months Ended March 31,	
	2023	2022
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	\$ 22,059	\$ 18,809
Supplemental Disclosures of Noncash Investing and Financing Information:		
Payment-in-kind interest added to principal of term loan	\$ —	\$ 1,763
Unpaid property and equipment	\$ 96	\$ 750
Transfers to noncontrolling interests	\$ (2,843)	\$ (317)
Reconciliation of Cash, Cash Equivalents and Restricted Cash:		
Cash and cash equivalents	\$407,368	\$371,550
Restricted cash	25,503	—
Restricted cash — Included in “Prepaid expenses and other current assets”	—	177
Restricted cash — Included in “Other assets”	2,238	2,466
Total cash, cash equivalents and restricted cash at end of period shown in the condensed consolidated statements of cash flows	<u>\$435,109</u>	<u>\$374,193</u>

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (BridgeBio) is a commercial-stage biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. BridgeBio’s pipeline of development programs ranges from early science to advanced clinical trials. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information visit bridgebio.com and follow us on [LinkedIn](#) and [Twitter](#).

BridgeBio Pharma, Inc. Forward-Looking Statements

This press release contains forward-looking statements. Statements in this press release 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 (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” “on track,” “remains” and variations of such words or similar expressions. 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 and therapeutic potential of our programs and product candidates, including the timing and success of our RAS program, including an IND application planned for first-in-class direct KRAS^{G12C} (ON) inhibitor BBO-8520 in second half of 2023, the timing of a Phase 3 trial of BBP-418 in patients with LGMD2I, intended to be initiated in mid-2023, and the potentially-addressable population of BBP-418 in the United States and European Union; the potential of infigratinib for achondroplasia to have a potential of best-in-class efficacy with well-tolerated safety profile and to capture a significant share of the market based on blinded market research, if approved; the timing and success of additional trials of encaleret for ADH1, including the continued proceeding of Phase 3 CALIBRATE trial of encaleret

for ADH1; the timing of announcement of topline data from CALIBRATE, expected in the first half of 2024; the success of encalet (if approved), including its potential to be the first therapy specifically indicated for the treatment of ADH1; the availability and success of topline results from the month 30 endpoint of our Phase 3 ATTRIBUTE-CM trial of acoramidis, expected in late July, 2023; the continuation and progress of our ongoing Phase 1/2 trial of BBP-631 for CAH, with a planned data update by the end of 2023; the continued evaluation of restructuring alternatives to drive operational changes in business processes, efficiencies, and cost savings, as well as our anticipated cash runway, 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. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a number of risks, uncertainties and assumptions, including, but not limited to, initial and ongoing data from our preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations our product candidates are designed to treat not being as large as anticipated, the design and success of ongoing and planned clinical trials, future regulatory filings, approvals and/or sales, despite having ongoing and future interactions with the FDA or other regulatory agencies to discuss potential paths to registration for our product candidates, the FDA or such other regulatory agencies not agreeing with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of our collaborations, the Company's ability to obtain additional funding under our credit facility, potential volatility in our share price, uncertainty regarding any impacts due to COVID-19, such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the impacts of current macroeconomic and geopolitical events, including changing conditions from hostilities in Ukraine, increasing rates of inflation and rising interest rates, on business operations and expectations, as well as those risks set forth in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2022 and our other filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release, and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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