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): February 22, 2024

BridgeBio Pharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38959**	**84-1850815**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
3160 Porter Dr., Suite 250 Palo Alto, CA		**94304**
(Address of Principal Executive Offices)		**(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 2.02 Results of Operations and Financial Condition.

On February 22, 2024, BridgeBio Pharma, Inc. reported recent business updates and its financial results for the fourth quarter and full year ended December 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	Description
99.1	Press Release dated February 22, 2024, 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.

BridgeBio Pharma, Inc.

Date: February 22, 2024

By: /s/ Brian C. Stephenson

Brian C. Stephenson, Ph.D., CFA
Chief Financial Officer

BridgeBio Pharma Reports Fourth Quarter and Full Year 2023 Financial Results and Business Update

- Submitted New Drug Application (NDA) to US Food and Drug Administration (FDA) for acoramidis for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM) based on positive results of Phase 3 ATTRibute-CM trial, which were published in the New England Journal of Medicine; NDA has been accepted for review with a PDUFA date of November 29, 2024; Marketing Authorization Application (MAA) for acoramidis has also been accepted by the European Medicines Agency (EMA)

- Presented additional data from ATTRibute-CM at the American Heart Association Scientific Sessions, demonstrating separation at Month 3 of the placebo and acoramidis time-to-first-event Kaplan-Meier curves for a composite of all-cause mortality (ACM) and cardiovascular-related hospitalization (CVH); separation was sustained through Month 30 and represents the most rapid clinical benefit on the composite endpoint of ACM and CVH in ATTR-CM patients to the Company's knowledge

- Shared positive results of single-arm Phase 3 study of acoramidis in Japanese ATTR-CM patients, including no mortality reported over the 30 month acoramidis treatment period

- PROPEL 3, the Company's Phase 3 study of infigratinib for achondroplasia continues to enroll with full enrollment expected in 2024; the Company has also announced a partnership granting Kyowa Kirin exclusive license on infigratinib for skeletal dysplasias in Japan in exchange for an upfront payment of $100 million, royalties up to the high twenties percent, and additional milestone-based payments

- FORTIFY, the Company's Phase 3 study BBP-418 for limb-girdle muscular dystrophy type 2I (LMGD2I), continues to enroll, with full enrollment of interim analysis population expected in 2024

- CALIBRATE, the Company's Phase 3 study of encaleret for autosomal dominant hypocalcemia type 1 (ADH1) continues to enroll, with full enrollment expected in 2024 and topline data expected in 2025

- Secured up to $1.25 billion of capital from Blue Owl and CPP investments, including $500 million in cash in exchange for a 5% royalty on future global net sales of acoramidis and a $450 million credit facility from Blue Owl that refinanced existing senior secured credit, extending maturity from 2026 to 2029 subject to certain conditions

- Ended the quarter with $393 million in cash, cash equivalents, and short-term restricted cash, and $59 million of investments in equity securities

Palo Alto, CA – February 22, 2024 – 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 fourth quarter and full year ended December 31, 2023, and provided an update on the Company's operations.

"Our focus this year is executing on the launch of acoramidis for patients with ATTR cardiomyopathy," said Neil Kumar, Ph.D., founder and CEO of BridgeBio. "At the same time, we are also focused on fully enrolling three ongoing Phase 3 clinical trials by the end of 2024. Finally, we hope that reading out potentially exciting data from our Phase 1/2 trial in congenital adrenal hyperplasia later this year will let us take the next step in serving that patient community."

BridgeBio's key programs:

- **Acoramidis (AG10) – Transthyretin (TTR) stabilizer for transthyretin amyloid cardiomyopathy (ATTR-CM):**
  - The Company filed an NDA for acoramidis for the treatment of ATTR-CM with the US FDA; the NDA was accepted for review with a PDUFA date of November 29, 2024. The Company has also filed a Marketing Authorization Application for acoramidis with the EMA, which has been accepted for review.
  - The regulatory filings were based on data from the Phase 3 ATTRibute-CM study, which met its primary endpoint (Win Ratio of 1.8) with a highly statistically significant p-value ($p<0.0001$). Additional results from ATTRibute-CM include:
    - An 81% survival rate on acoramidis, which approaches the survival rate in the age-matched U.S. database (~85%), and a 0.29 mean annual CVH rate on acoramidis, which approaches the annual hospitalization rate observed in the broader U.S. Medicare population (~0.26);
    - Improvements from baseline observed for a large proportion of participants treated with acoramidis on laboratory and functional measures including n-terminal prohormone of brain natriuiretic peptide (NT-proBNP) and 6-minute walk distance;
    - Rapid clinical benefit on the composite endpoint of ACM and CVH in participants treated with acoramidis, demonstrated by placebo and acoramidis time-to-first event Kaplan-Meier curves for a composite of ACM and CVH that separated at Month 3 and continued to diverge steadily through Month 30 as presented at the American Heart Association Scientific Sessions in November 2023; and
    - Acoramidis was well-tolerated with no safety signals of potential clinical concern identified.
  - The Company also shared positive results of an open-label, single-arm Phase 3 study conducted in Japan by licensing partner Alexion, AstraZeneca Rare Disease, including that no mortality was reported over the 30 month acoramidis treatment period.
  - Additional detailed results of ATTRibute-CM are planned for presentation at 2024 medical meetings.
- **Low-dose infigratinib – FGFR1-3 inhibitor for achondroplasia and hypochondroplasia:**
  - In December 2023, the Company announced the dosing of the first child in PROPEL 3, its global Phase 3 registrational study of infigratinib in achondroplasia.
  - In February 2024, the Company announced a partnership with Kyowa Kirin wherein the Company grants Kyowa Kirin an exclusive license to develop and commercialize infigratinib for achondroplasia, hypochondroplasia, and other skeletal dysplasias in Japan; in exchange, the Company will receive an upfront payment of $100 million as well as royalties up to the high-twenties percent on sales of infigratinib in Japan, with the potential for additional milestone-based payments.

- The Company is committed to exploring the potential of infigratinib on the wider medical and functional impacts of achondroplasia, hypochondroplasia and other skeletal dysplasias, and anticipates initiating its clinical program for hypochondroplasia in 2024.

- **BBP-418 – Glycosylation substrate for limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9):**
  - FORTIFY, the global Phase 3 registrational trial of BBP-418, continues to enroll in the U.S. with clinical trial sites planned for Europe and Australia. Full enrollment of the interim analysis population is expected in 2024. The Company believes there is potential to pursue Accelerated Approval for BBP-418 based on recent interactions with the FDA on the use of glycosylated αDG levels as a surrogate endpoint.

- **Encaleret – Calcium-sensing receptor (CaSR) inhibitor for autosomal dominant hypocalcemia type 1 (ADH1):**
  - CALIBRATE, the Phase 3 clinical trial of encaleret, continues to enroll; the Company anticipates sharing topline data from CALIBRATE in 2025.

Recent Corporate Updates:

- **Secured up to $1.25 billion of capital from Blue Owl and CPP Investments:** The raise includes $500 million in cash from Blue Owl and CPP Investments available upon FDA approval of acoramidis in exchange for a 5% royalty on future global net sales of acoramidis, as well as a $450 million credit facility from Blue Owl that refinanced existing senior secured credit, extending maturity from 2026 to 2029 subject to certain conditions.

Fourth Quarter and Full Year 2023 Financial Results:

Cash, Cash Equivalents, Marketable Securities and Short-term Restricted Cash

Cash, cash equivalents and short-term restricted cash, totaled $392.6 million as of December 31, 2023, compared to cash, cash equivalents, marketable securities and short-term restricted cash of $466.2 million as of December 31, 2022. The net decrease of $73.6 million in cash, cash equivalents, marketable securities and short-term restricted cash was primarily attributable to net cash used in operating activities of $527.7 million and $6.9 million in repurchase of shares to satisfy tax withholdings, primarily offset by net proceeds received of $449.8 million from various equity financings, $6.0 million from stock option exercises, and $3.4 million from common stock issuances under our employee stock purchase plan during the year ended December 31, 2023.

Revenue

Revenue for the three months and year ended December 31, 2023 were $1.7 million and $9.3 million, respectively, as compared to $1.9 million and $77.6 million for the same periods in the prior year, respectively. The net decreases of $0.2 million and $68.3 million for the three months and year ended December 31, 2023, respectively, compared to the same periods in the prior year, were primarily due to license revenue recognized in 2022 upon the transfer of the license in accordance with the Navire-BMS License Agreement which was entered into in May 2022.

Operating Costs and Expenses

Operating costs and expenses for the three months and year ended December 31, 2023 were $179.2 million and $616.7 million, respectively, compared to $131.1 million and $589.9 million, for the same periods in the prior year, respectively.

The overall increase of $48.1 million in operating costs and expenses for the three months ended December 31, 2023, compared to the same period in the prior year, was primarily due to an increase of $39.3 million in research and development and other expenses (R&D) to advance the Company's pipeline of development programs, an increase of $15.7 million in selling, general and administrative (SG&A) expenses to support commercialization readiness efforts, offset by a decrease of $6.9 million in restructuring, impairment and related charges given that the majority of the restructuring initiatives occurred in the prior year.

The overall increase of $26.8 million in operating costs and expenses for the year ended December 31, 2023 , compared to the same period in the prior year, was primarily due to an increase of $55.2 million in R&D expenses to advance the Company's pipeline of development programs, an increase of $7.4 million in SG&A expenses to support commercialization readiness efforts, offset by a decrease of $35.8 million in restructuring, impairment and related charges given that the majority of the restructuring initiatives occurred in the prior year.

Restructuring, impairment and related charges for the three months and year ended December 31, 2023, amounted to $0.8 million and $7.9 million, respectively. These charges primarily consisted of winding down, exit costs, and severance and employee-related costs. Restructuring, impairment and related charges for the same periods in the prior year were $7.7 million and $43.8 million, respectively. These charges primarily consisted of impairments and write-offs of long-lived assets, severance and employee-related costs, and exit and other related costs.

Stock-based compensation expenses included in operating costs and expenses for the three months ended December 31, 2023 were $37.1 million, of which $22.5 million is included in R&D expenses, and $14.6 million is included in SG&A expenses. Stock-based compensation expenses included in operating costs and expenses for the same period in the prior year were $22.6 million, of which $8.9 million is included in R&D expenses, and $13.6 million is included in SG&A expenses.

Stock-based compensation expenses included in operating costs and expenses for the year ended December 31, 2023 were $115.0 million, of which $61.6 million is included in R&D expenses, and $53.4 million is included in SG&A expenses. Stock-based compensation expenses included in operating costs and expenses for the same period in the prior year were $93.8 million, of which $38.0 million is included in R&D expenses, $54.7 million is included in SG&A expenses, and $1.2 million is included in restructuring, impairment and related charges.

“Coming off of our recent royalty financing, we find ourselves well capitalized to launch acoramidis this year alongside strong new partners who share our confidence in acoramidis’ potential in the ATTR-CM market,” said Brian Stephenson, Ph.D., CFA, Chief Financial Officer of BridgeBio. “We are excited for this launch, as well as for the continued advancement of our late stage pipeline, which we hope will allow us to serve patients with genetic diseases both directly with the advancement of those medicines towards the market as well as by diversifying our top line revenue and enabling reinvestment into the R&D and business development opportunities that will allow us to be sustainable in the long term.”

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	(1)
Revenue	$ 1,745	$ 1,870	$ 9,303	$ 77,648
Operating costs and expenses:				
Research, development and other expenses	130,824	91,549	458,157	402,896
Selling, general and administrative	47,583	31,862	150,590	143,189
Restructuring, impairment and related charges	754	7,691	7,926	43,765
Total operating costs and expenses	179,161	131,102	616,673	589,850
Loss from operations	(177,416)	(129,232)	(607,370)	(512,202)
Other income (expense), net:				
Interest income	5,578	4,092	18,038	7,542
Interest expense	(20,268)	(19,990)	(81,289)	(80,438)
Gain from sale of priority review voucher, net	—	—	—	107,946
Other income (expense), net	21,778	4,560	17,370	(7,500)
Total other income (expense), net	7,088	(11,338)	(45,881)	27,550
Net loss	(170,328)	(140,570)	(653,251)	(484,652)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	2,180	2,979	10,049	3,469
Net loss attributable to common stockholders of BridgeBio	$ (168,148)	$ (137,591)	$ (643,202)	$ (481,183)
Net loss per share, basic and diluted	$ (0.96)	$ (0.92)	$ (3.95)	$ (3.26)
Weighted-average shares used in computing net loss per share, basic and diluted	174,462,332	149,344,380	162,791,511	147,473,076

Stock-based Compensation	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	(1)
Research, development and others	$ 22,495	$ 8,941	$ 61,647	$ 37,987
Selling, general and administrative	14,638	13,643	53,369	54,669
Restructuring, impairment and related charges	—	—	—	1,172
Total stock-based compensation	$ 37,133	$ 22,584	$ 115,016	$ 93,828

(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 Balance Sheets
(In thousands)

	December 31, 2023	December 31, 2022
	(Unaudited)	(1)
Assets		
Cash, cash equivalents and marketable securities	$ 375,935	$ 428,269
Investment in equity securities	58,949	43,653
Receivable from licensing and collaboration agreements	1,751	17,079
Short-term restricted cash	16,653	37,930
Prepaid expenses and other current assets	24,305	21,922
Property and equipment, net	11,816	14,569
Operating lease right-of-use assets	8,027	10,678
Intangible assets, net	26,319	28,712
Other assets	22,625	20,224
Total assets	$ 546,380	$ 623,036
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Accounts payable	$ 10,655	$ 11,558
Accrued and other liabilities	129,061	106,195
Operating lease liabilities	13,109	15,949
2029 Notes, net	736,905	734,988
2027 Notes, net	543,379	541,634
Term loan, net	446,445	430,993
Other long-term liabilities	9,361	26,643
Redeemable convertible noncontrolling interests	478	(1,589)
Total BridgeBio stockholders' deficit	(1,354,257)	(1,254,617)
Noncontrolling interests	11,244	11,282
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	$ 546,380	$ 623,036

(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)

	Year Ended December 31,	
	2023	**2022**
	(Unaudited)	**(1)**
Operating activities:		
Net loss	$ (653,251)	$ (484,652)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	108,710	91,559
Depreciation and amortization	6,494	6,771
Noncash lease expense	4,032	5,172
Accrual of payment-in-kind interest on term loan	10,207	13,562
Loss on deconsolidation of PellePharm	1,241	—
(Gain) loss from investment in equity securities, net	(18,314)	8,222
Fair value of shares issued under a license agreement	—	4,567
Accretion of debt	8,907	8,570
Fair value adjustment of warrants	(984)	1,571
Loss on sale of certain assets	—	6,261
Impairment of long-lived assets	—	12,720
Gain from sale of priority review voucher, excluding transaction costs	—	(110,000)
Gain from recognition of receivable from licensing and collaboration agreement	—	(12,500)
Other noncash adjustments	181	604
Changes in operating assets and liabilities:		
Receivable from licensing and collaboration agreements	15,328	15,169
Prepaid expenses and other current assets	(2,702)	7,671
Other assets	(1,546)	10,971
Accounts payable	2,780	(349)
Accrued compensation and benefits	7,802	(2,362)
Accrued research and development liabilities	(9,855)	(4,309)
Operating lease liabilities	(4,829)	(6,245)
Deferred revenue	(5,438)	15,262
Accrued professional and other liabilities	3,517	(7,729)
Net cash used in operating activities	(527,720)	(419,494)
Investing activities:		
Purchases of marketable securities	(29,726)	(137,493)
Maturities of marketable securities	82,550	479,688
Purchases of investment in equity securities	(107,538)	(55,562)
Sales of investment in equity securities	110,556	52,835
Decrease in cash and cash equivalents resulting from deconsolidation of PellePharm	(503)	—
Payment for intangible asset	—	(1,500)
Proceeds from sale of priority review voucher	—	110,000
Proceeds from sale of certain assets	—	10,000
Purchases of property and equipment	(1,306)	(4,821)
Net cash provided by investing activities	54,033	453,147
Financing activities:		
Proceeds from issuance of common stock through Private Placement offering, net	240,796	—
Proceeds from issuance of common stock through Follow-on offering, net	144,049	—
Proceeds from issuance of common stock through ATM offering, net	64,965	4,852
Transactions with noncontrolling interests	(801)	—
Repayment of term loan	—	(20,486)
Proceeds from BridgeBio common stock issuances under ESPP	3,398	2,558
Repurchase of RSU shares to satisfy tax withholding	(6,880)	(1,561)
Proceeds from stock option exercises, net of repurchases	6,008	666
Other financing activities	—	837
Net cash provided by (used in) financing activities	451,535	(13,134)
Net increase (decrease) in cash, cash equivalents and restricted cash	(22,152)	20,519
Cash, cash equivalents and restricted cash at beginning of period	416,884	396,365
Cash, cash equivalents and restricted cash at end of period	$ 394,732	$ 416,884

	Year Ended December 31,	
	2023	2022
	(Unaudited)	(1)
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	$ 61,108	$ 54,443
Supplemental Disclosures of Noncash Investing and Financing Information:		
Unpaid property and equipment	$ 100	$ 47
Recognized intangible asset recorded in "Other accrued and other long-term liabilities"	$ —	$ 11,000
Transfers (to) from noncontrolling interests	$ (10,534)	$ (3,512)
Payment-in-kind interest added to principal of term loan	$ —	$ 1,763
Reconciliation of Cash, Cash Equivalents and Restricted Cash:		
Cash and cash equivalents	$ 375,935	$ 376,689
Short-term restricted cash	16,653	37,930
Restricted cash — Included in "Other assets"	2,144	2,265
Total cash, cash equivalents and restricted cash at end of periods	$ 394,732	$ 416,884

(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.

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," "continues," "estimates," "expects," "hopes," "intends," "may," "plans," "projects," "remains," "seeks," "should," "will," 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, market potential of our programs and product candidates, including the statements in Dr. Kumar's and Dr. Stephenson's quotes regarding the potential commercial launch of acoramidis (if approved), continued advancement in our pipeline, including enrollments in clinical trials and anticipated readout, and other benefits resulting from recent financing; the statements related to the FDA's planned actions regarding our NDA for acoramidis for the treatment of ATTR-CM; the potential outcomes of regulatory reviews by the FDA and the EMA; the timing and success of our clinical development programs, including the progress of our clinical development program for acoramidis for patients with ATTR-CM, and our plan for, and the expected timing of, presenting additional detailed results of ATTRibute-CM study at medical meetings; the potential success of our partnership granting Kyowa Kirin an exclusive license on infigratinib for skeletal dysplasias in Japan and the potential payments we may receive under the license; the continuation of PROPEL 3, our Phase 3 study of infigratinib for achondroplasia and the

expected timing for full enrollment in the study; our commitment to exploring the potential of infigratinib and the expectation and timing of the initiation of our clinical program for hypochondroplasia; the continuation and progress of FORTIFY, the Phase 3 trial of BBP-418 for LGMD2I, including the ongoing enrollment in the United States, the expectation to enroll in clinical trial sites planned in Europe and Australia, the expectation and timing of full enrollment of the interim analysis population, and the potential to pursue Accelerated Approval for BBP-418 based on recent interactions with the FDA; the continued enrollment in CALIBRATE, the Phase 3 clinical trial of encaleret, and the expectation and timing of full enrollment and sharing topline data from CALIBRATE; the Company's financial performance, capitalization status, strategy, business plans and goals 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, including through less dilutive sources of capital than equity financings, potential volatility in our share price, uncertainty regarding any impacts due to global health emergencies such as COVID-19, including 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 and in Israel and the Gaza Strip, 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 most recent Annual Report on Form 10-K 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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