



NEWS RELEASE

bridgebio pharma reports second quarter 2024 financial results and business update

2024-08-01

- Acoramidis demonstrated a significant impact on mortality, hospitalizations, and quality of life
 - Starting at Month 3, patients taking acoramidis showed meaningful and sustained improvement in time to first event (CVH or ACM)
 - Acoramidis demonstrated a 42% reduction in composite CVH and ACM events relative to placebo by Month 30
 - Increased serum TTR levels by Day 28 were correlated with a reduced risk of events (ACM, CVM, and CVH) through Month 30
 - Acoramidis resulted in a statistically significant reduction in ACM in the intention-to-treat (ITT) population at Month 30
- Shared +2.50 cm/yr annualized height velocity (AHV) at Month 18 in Cohort 5 of PROPEL 2, the Phase 2 study of infigratinib in achondroplasia, as well as the first ever reported statistically significant improvement in body proportionality
- The first child consented in ACCEL, the observational run-in study for infigratinib in children living with hypochondroplasia, a skeletal dysplasia closely related to achondroplasia
- The Company surpassed its interim analysis enrollment target for its Phase 3 FORTIFY study of BBP-418 in individuals living with limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9)

- The Company ended the quarter with \$587 million in cash, cash equivalents, marketable securities and short-term restricted cash

PALO ALTO, Calif., Aug. 01, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio or the Company), a commercial-stage biopharmaceutical company focused on genetic diseases, today reported its financial results for the second quarter ended June 30, 2024, and provided an update on the Company's operations.

"Our team has continued its preparation for the commercial launch of acoramidis while also executing against our goal of fully enrolling our three Phase 3 clinical programs by the end of 2024. We are well positioned to launch acoramidis and achieve three readouts in 2025. Our differentiated capability to develop multiple candidates for genetic-based diseases provides a unique opportunity to create significant value for patients and shareholders," said Dr. Neil Kumar, CEO and Founder of BridgeBio.

Pipeline overview:

Program	Status	Next expected milestone
Acoramidis for ATTR-CM	NDA filed with FDA	November 29, 2024 PDUFA date
Encalret for ADH1	Enrolling CALIBRATE, Phase 3 study	Enrollment completion in 2024
BBP-418 for LGMD2I/R9	Enrolling FORTIFY, Phase 3 study	Enrollment completion in 2024
Low-dose infigratinib for achondroplasia	Enrolling PROPEL 3, Phase 3 study	Enrollment completion in 2024
Low-dose infigratinib for hypochondroplasia	Enrolling observational run-in for ACCEL 2, Phase 2 study	Enrollment completion date to be announced
BBP-631 for congenital adrenal hyperplasia (CAH)	Dose finding / analysis in Phase 2 study	Program update in August 2024
BBP-812 for Canavan disease	Enrolling at high dose in Phase 1/2 study	Key regulatory interactions

Program updates:

- Acoramidis (AG10) – Transthyretin (TTR) stabilizer for transthyretin amyloid cardiomyopathy (ATTR-CM):
 - During the 2024 International Symposium of Amyloidosis (ISA), five new analyses were disclosed through oral presentations and posters, discussing the following:
 - Acoramidis treatment resulted in increased serum transthyretin (TTR) levels by Day 28 that were sustained and were correlated with a reduced risk of all-cause mortality (ACM), cardiovascular mortality (CVM), and cardiovascular hospitalization (CVH) in ATTR-CM participants through Month 30.
 - Acoramidis treatment resulted in a significant improvement in the composite endpoint of ACM and CVH in ATTR-CM participants, with benefit evident as early as Month 3.

- In ATTRibute-CM, participants with at least one CVH had a significantly higher risk of mortality, highlighting the need for ATTR-CM treatments that reduce the risk of CVH.
- BridgeBio also shared the rationale and design of ACT-EARLY, the acoramidis ATTR amyloidosis prevention trial, which it expects to initiate later this year.
- At this year's European Society of Cardiology Heart Failure (ESC-HF) Congress 2024, BridgeBio shared four positive analyses, which included the following data:
 - In a pre-specified Cochran-Mantel-Haenszel sensitivity analysis applied to the entire ITT population of the study (N=632), acoramidis significantly reduced ACM (p=0.04), with no safety signals of potential clinical concern.
 - Among ATTRibute-CM participants enrolled with Stage 4 chronic kidney disease (CKD) (N=21), acoramidis treatment was associated with proportionally fewer deaths compared with placebo, with no safety signals of potential clinical concern.
 - At Month 30 of the ATTRibute-CM study, acoramidis treatment resulted in a statistically significant and clinically important reduction in the progressive decline in health-related quality of life as assessed by the EuroQoL Health Outcomes Assessment tool, EQ-5D-5L.
 - Acoramidis treatment also reduced the decline in health status and quality of life as shown by statistically significant and clinically meaningful benefits in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score and supported by numerical and consistent benefits in individual KCCQ domains.
 - In ATTRibute-CM, acoramidis significantly improved NT-proBNP indices that can be a signal of ATTR-CM disease progression and be predictive of subsequent mortality risk.
- During the 2024 American College of Cardiology (ACC), BridgeBio presented cardiac magnetic resonance (CMR) imaging evidence consistent with clinical improvement observed in the ATTRibute-CM. The data demonstrate that targeting near-complete TTR stabilization with acoramidis may enable cardiac remodeling and functional recovery in patients with ATTR-CM.
- Encaleret – Calcium-sensing receptor (CaSR) inhibitor for autosomal dominant hypocalcemia type 1 (ADH1):
 - CALIBRATE, the Phase 3 clinical trial of encaleret in ADH1, continues to enroll; the Company anticipates sharing topline data from CALIBRATE in 2025.
- BBP-418 – Glycosylation substrate for limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9):
 - BridgeBio has surpassed its interim analysis enrollment target for its Phase 3 FORTIFY study of BBP-418 in individuals living with LGMD2I/R9, with top-line results from the interim analysis expected in 2025.

- Recent Type C interactions with U.S. FDA focused on the validated glycosylated alpha-dystroglycan (α DG) bioassay and our interim analysis plans reinforce BridgeBio's belief that there is potential to pursue Accelerated Approval for BBP-418.
- Rare Pediatric Disease Designation for BBP-418 highlights that LGMD2I/R9 is a rare disease with serious manifestations, which primarily impacts children. If BBP-418 is approved, BridgeBio may qualify for a Priority Review Voucher, which can be applied to another therapy in the Company's pipeline for a shorter timeline during the review process of a NDA or can be sold to another company looking to receive priority review for one of its applications.
- Low-dose infigratinib – FGFR1-3 inhibitor for achondroplasia and hypochondroplasia:
 - BridgeBio shared data from Month 12 and 18 for Cohort 5 of PROPEL 2 (0.25 mg/kg/day), its Phase 2 trial in achondroplasia with the oral treatment, infigratinib, with results including:
 - A statistically significant and sustained increase in AHV, with a mean change from baseline of +2.51 cm/yr at Month 12, and +2.50 cm/yr at Month 18 ($p=0.0015$).
 - At Month 18, there was a statistically significant improvement in body proportionality (p -value of 0.001). The mean upper to lower body segment ratio was 1.88 at Month 18, as compared to 2.02 at baseline.
 - Infigratinib continues to be well-tolerated as a single daily oral therapy with no adverse events (AEs) assessed as treatment-related in any participant in Cohort 5.
 - Infigratinib for achondroplasia was granted Fast Track Designation and Rare Pediatric Drug Designation by the U.S. FDA. If infigratinib is approved, BridgeBio may qualify for a Priority Review Voucher.
 - In May 2024, the first participant consented to be part of ACCEL, the observational run-in study for infigratinib in children living with hypochondroplasia.

Second Quarter 2024 Financial Results:

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

Cash, cash equivalents, marketable securities and short-term restricted cash, totaled \$587.2 million as of June 30, 2024, compared to \$392.6 million of cash, cash equivalents and short-term restricted cash as of December 31, 2023. The \$194.6 million net increase in cash, cash equivalents, marketable securities and short-term restricted cash was primarily attributable to net proceeds received from the term loan under the credit facility with Blue Owl of \$434.0 million, net proceeds received from various equity financings of \$314.8 million, proceeds from the sale of investments in equity securities of \$63.2 million, and special cash dividends received from investments in equity securities of \$25.7 million. These were primarily offset by refinancing of the Company's previous senior secured

credit term loan, inclusive of prepayment fees and exit-related costs in aggregate of \$473.4 million, net cash used in operating activities of \$144.8 million, purchases of equity securities of \$20.3 million, and repurchase of shares to satisfy tax withholdings of \$4.7 million during the six months ended June 30, 2024.

Revenue

Revenue for the three and six months ended June 30, 2024 were \$2.2 million and \$213.3 million, respectively, as compared to \$1.6 million and \$3.5 million for the same periods in the prior year.

The increase of \$0.6 million in revenue for the three months ended June 30, 2024, compared to the same period in the prior year, was primarily due to the recognition of services revenue under the exclusive license and collaboration agreements with Bayer and Kyowa Kirin. Revenue for the three months ended June 30, 2023 primarily consists of the recognition of services revenue under the Navire-BMS License Agreement, which terminated effective June 2024.

The increase of \$209.8 million in revenue for the six months ended June 30, 2024, compared to the same period in the prior year, was primarily due to \$202.9 million from recognition of non-refundable upfront payments and service revenue under the Bayer and the Kyowa Kirin exclusive license and collaboration agreements.

Operating Costs and Expenses

Operating costs and expenses for the three and six months ended June 30, 2024 were \$177.7 million and \$388.5 million, respectively, compared to \$147.7 million and \$275.7 million for the same periods in the prior year.

The overall increase of \$30.0 million in operating costs and expenses for the three months ended June 30, 2024, compared to the same period in the prior year, was primarily due to an increase of \$23.4 million in selling, general and administrative (SG&A) expenses mainly to support commercialization readiness efforts, an increase of \$7.2 million in research and development and other expenses (R&D) to advance the Company's pipeline of research and development programs, offset by a decrease of \$0.6 million in restructuring, impairment and related charges.

The overall increase of \$112.8 million in operating costs and expenses for the six months ended June 30, 2024, compared to the same period in the prior year, was primarily due to an increase of \$58.1 million in SG&A expenses mainly to support commercialization readiness efforts, and an increase of \$55.3 million in R&D expenses to advance the Company's pipeline of research and development programs, offset by a decrease of \$0.6 million in restructuring, impairment and related charges. Operating costs and expenses for the six months ended June 30, 2024, include \$22.5 million of nonrecurring deal-related costs for transactions that were closed during the three months ended March 31, 2024.

Restructuring, impairment and related charges for the three and six months ended June 30, 2024 amounted to \$2.9 million and \$6.3 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. Restructuring, impairment and related charges for the same periods in the prior year was \$3.5 million and \$6.9 million, respectively. These charges primarily consisted of winding down, exit costs, and severance and employee-related costs.

Stock-based compensation expenses included in operating costs and expenses for the three months ended June 30, 2024 were \$21.5 million, of which \$4.9 million is included in R&D expenses, \$16.5 million is included in SG&A expenses, and \$0.1 million is included in Restructuring expenses. Stock-based compensation expenses included in operating costs and expenses for the same period in the prior year were \$27.2 million, of which \$13.2 million is included in R&D expenses, and \$14.0 million is included in SG&A expenses.

Stock-based compensation expenses included in operating costs and expenses for the six months ended June 30, 2024 were \$50.3 million, of which \$17.7 million is included in R&D expenses, \$32.5 million is included in SG&A expenses, and \$0.1 million is included in Restructuring expenses. Stock-based compensation expenses included in operating costs and expenses for the same period in the prior year were \$50.7 million, of which \$25.0 million is included in R&D expenses, and \$25.7 million is included in SG&A expenses.

Total Other Income (Expense), net

Total other income (expense), net for the three and six months ended June 30, 2024 were \$100.0 million and \$63.5 million, respectively, compared to (\$14.6) million and (\$31.2) million for the same periods in the prior year.

The increase in total other income (expense), net of \$114.6 million for the three months ended June 30, 2024, compared to the same period in the prior year, was primarily due to the Company's gain on deconsolidation of a subsidiary of \$126.3 million. This was partially offset by a net loss from an equity method investment of \$7.9 million and an increase in interest expense of \$2.3 million.

The increase in total other income (expense), net of \$94.7 million for the six months ended June 30, 2024, compared to the same period in the prior year, was primarily due to the Company's gain on deconsolidation of a subsidiary of \$126.3 million and an increase in other income (expense), net of \$8.1 million mainly from income or mark to market fair value adjustments from the Company's investments in equity securities. These were partially offset by a loss on extinguishment of debt of \$26.6 million, a net loss from an equity method investment of \$7.9 million and an increase in interest expense of \$5.7 million.

Net Loss Attributable to Common Stockholders of BridgeBio and Net Loss per Share

For the three months and six months ended June 30, 2024, the Company recorded a net loss attributable to common stockholders of BridgeBio of \$73.5 million and \$108.7 million, respectively, compared to \$157.9 million and \$298.1 million, respectively for the three months and six months ended June 30, 2023.

For the three months and six months ended June 30, 2024, the Company reported a net loss per share of \$0.39 and \$0.59, respectively compared to \$0.98 and \$1.90, respectively for the three months and six months ended June 30, 2023.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Revenue	\$ 2,168	\$ 1,641	\$ 213,288	\$ 3,467
Operating costs and expenses:				
Research, development and other expenses	115,293	108,087	256,863	201,599
Selling, general and administrative	59,523	36,122	125,330	67,230
Restructuring, impairment and related charges	2,891	3,531	6,291	6,900
Total operating costs and expenses	<u>177,707</u>	<u>147,740</u>	<u>388,484</u>	<u>275,729</u>
Loss from operations	(175,539)	(146,099)	(175,196)	(272,262)
Other income (expense), net:				
Interest income	5,195	4,514	9,270	8,667
Interest expense	(22,937)	(20,594)	(46,408)	(40,715)
Gain on deconsolidation of a subsidiary	126,294	—	126,294	—
Loss on extinguishment of debt	—	—	(26,590)	—
Net loss from equity method investment	(7,925)	—	(7,925)	—
Other income (expense), net	(632)	1,476	8,851	875
Total other income (expense), net	<u>99,995</u>	<u>(14,604)</u>	<u>63,492</u>	<u>(31,173)</u>
Net loss	(75,544)	(160,703)	(111,704)	(303,435)
Net loss attributable to redeemable convertible noncontrolling interests and noncontrolling interests	2,088	2,804	3,032	5,380
Net loss attributable to common stockholders of BridgeBio	<u>\$ (73,456)</u>	<u>\$ (157,899)</u>	<u>\$ (108,672)</u>	<u>\$ (298,055)</u>
Net loss per share, basic and diluted	<u>\$ (0.39)</u>	<u>\$ (0.98)</u>	<u>\$ (0.59)</u>	<u>\$ (1.90)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>187,586,680</u>	<u>160,535,435</u>	<u>183,145,995</u>	<u>156,645,838</u>

Stock-based Compensation

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Research, development and other expenses	\$ 4,937	\$ 13,229	\$ 17,716	\$ 25,008
Selling, general and administrative	16,471	13,947	32,542	25,645
Restructuring, impairment and related charges	43	—	43	—
Total stock-based compensation	<u>\$ 21,451</u>	<u>\$ 27,176</u>	<u>\$ 50,301</u>	<u>\$ 50,653</u>

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

	<u>June 30,</u> 2024	<u>December 31,</u> 2023
Assets	(Unaudited)	(1)
Cash, cash equivalents and marketable securities	\$ 447,771	\$ 375,935
Investments in equity securities	—	58,949
Receivables from licensing and collaboration agreements	660	1,751
Short-term restricted cash	139,409	16,653
Prepaid expenses and other current assets	28,396	24,305
Investment in nonconsolidated entity	117,006	-
Property and equipment, net	9,840	11,816
Operating lease right-of-use assets	7,267	8,027
Intangible assets, net	25,123	26,319
Other assets	18,903	22,625
Total assets	<u>\$ 794,375</u>	<u>\$ 546,380</u>
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Accounts payable	\$ 18,126	\$ 10,655
Accrued and other liabilities	96,517	122,965
Operating lease liabilities	11,682	13,109
Deferred revenue	32,059	9,823
2029 Notes, net	737,882	736,905
2027 Notes, net	544,270	543,379
Term loan, net	435,447	446,445
Other long-term liabilities	485	5,634
Redeemable convertible noncontrolling interests	(223)	478
Total BridgeBio stockholders' deficit	(1,092,925)	(1,354,257)
Noncontrolling interests	11,055	11,244
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	<u>\$ 794,375</u>	<u>\$ 546,380</u>

(1) The condensed consolidated financial statements as of and for the year ended December 31, 2023 are derived from the audited consolidated financial statements as of that date.

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

	<u>Six Months Ended June 30,</u>	
	<u>2024</u>	<u>2023</u>
Operating activities:		
Net loss	\$ (111,704)	\$ (303,435)
Adjustments to reconcile net loss to net cash used in operating activities:	-----	-----

Stock-based compensation	38,511	49,085
Loss on extinguishment of debt	26,590	—
Accretion of debt	3,683	4,580
Depreciation and amortization	3,170	3,270
Noncash lease expense	2,093	2,024
Accrual of payment-in-kind interest on term loan	—	6,742
Net loss from equity method investment	7,925	—
Loss (gain) on deconsolidation of subsidiaries	(126,294)	1,241
Gain from investment in equity securities, net	(8,136)	(2,399)
Fair value adjustment of warrants	—	(222)
Other noncash adjustments	(1,911)	(328)
Changes in operating assets and liabilities:		
Receivables from licensing and collaboration agreements	1,091	8,466
Prepaid expenses and other current assets	(6,506)	1,057
Other assets	942	32
Accounts payable	8,858	(4,098)
Accrued compensation and benefits	(8,378)	(11,071)
Accrued research and development liabilities	7,067	(11,322)
Operating lease liabilities	(2,981)	(2,443)
Deferred revenue	22,236	(3,184)
Accrued professional and other liabilities	(1,090)	4,330
Net cash used in operating activities	(144,834)	(257,675)
Investing activities:		
Purchases of marketable securities	(93,811)	(19,754)
Maturities of marketable securities	55,000	41,550
Purchases of investments in equity securities	(20,271)	(71,504)
Proceeds from sales of investments in equity securities	63,229	67,068
Proceeds from special cash dividends received from investments in equity securities	25,682	—
Payment for an intangible asset	(3,190)	—
Purchases of property and equipment	(749)	(440)
Decrease in cash and cash equivalents resulting from deconsolidation of subsidiaries	(98)	(503)
Net cash provided by investing activities	25,792	16,417
Financing activities:		
Proceeds from term loan under Financing Agreement	450,000	—
Issuance costs and discounts associated with term loan under Financing Agreement	(15,986)	—
Repayment of term loan under Loan and Security Agreement	(473,417)	—
Proceeds from issuance of common stock through public offerings, net	314,759	144,049
Proceeds from BridgeBio common stock issuances under ESPP	2,364	1,809
Proceeds from stock option exercises, net of repurchases	778	312
Repurchase of RSU shares to satisfy tax withholding	(4,679)	(1,715)
Other financing activities	—	4,563
Net cash provided by financing activities	273,819	149,018
Net increase (decrease) in cash, cash equivalents and restricted cash	154,777	(92,240)
Cash, cash equivalents and restricted cash at beginning of period	394,732	416,884
Cash, cash equivalents and restricted cash at end of period	<u>\$ 549,509</u>	<u>\$ 324,644</u>

	Six Months Ended June 30,	
	2024	2023
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	<u>\$ 49,046</u>	<u>\$ 28,738</u>
Supplemental Disclosures of Noncash Investing and Financing Information:		
Unpaid public offering issuance costs	<u>\$ 18</u>	<u>\$ —</u>
Deferred and unpaid issuance costs recorded to "Accrued and other liabilities"	<u>\$ 74</u>	<u>\$ —</u>
Unpaid property and equipment	<u>\$ 70</u>	<u>\$ 131</u>
Transfers to noncontrolling interests	<u>\$ (1,929)</u>	<u>\$ (5,940)</u>
Reconciliation of Cash, Cash Equivalents and Restricted Cash:		
Cash and cash equivalents	\$ 407,958	\$ 302,438
Restricted cash	139,409	19,930
Restricted cash — Included in "Other assets"	2,142	2,276
Total cash, cash equivalents and restricted cash at end of period shown in the condensed consolidated statements of cash flows	<u>\$ 549,509</u>	<u>\$ 324,644</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. 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](https://www.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 the Company's programs and product candidates, including the statements in Dr. Kumar's quote regarding the potential commercial launch of acoramidis (if approved) and the Company's goal of fully enrolling its three Phase 3 clinical programs, continued advancement in the Company's pipeline, including enrollments in clinical trials and anticipated readouts, and other benefits resulting from recent financing activities; the statements related to the FDA's planned actions regarding the Company's NDA for acoramidis for the treatment of ATTR-CM; the potential outcomes of regulatory interactions with and reviews by the FDA and the European Medicines Agency; the timing and success of the Company's clinical development programs, including the progress of the Company's clinical development program for acoramidis for patients with ATTR-CM, and the Company's plan for, and the expected timing of, initiation of ACT-EARLY, the Company's planned acoramidis ATTR amyloidosis prevention trial; the potential payments we may receive under the recent license agreement with Bayer and Kyowa Kirin; the continuation of PROPEL 3, the Company's Phase 3 study of infigratinib for achondroplasia and the expected timing for completion of the study; the Company's commitment to exploring the potential of infigratinib and expectation regarding the Company's clinical program for hypochondroplasia; the continuation and progress of FORTIFY, the Phase 3 trial of BBP-418 for LGMD2I/R9, including the expected receipt of top-line results from the interim analysis population, and the potential to pursue Accelerated Approval for BBP-418 based on recent interactions with the FDA; the Company's ability to qualify for Priority Review Vouchers with respect to BBP-418 and infigratinib; the continued enrollment in CALIBRATE, the Phase 3 clinical trial of encaleret, and the timing for sharing topline data from CALIBRATE; and the Company's financial performance, capitalization status, strategy, business

plans and goals reflect the Company's current views about the Company's plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Although the Company believes that its 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 the Company's preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations the Company's 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 the Company's product candidates, the FDA or such other regulatory agencies not agreeing with the Company's regulatory approval strategies, components of the Company's filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of the Company's collaborations, the Company's ability to obtain additional funding, including through less dilutive sources of capital than equity financings, potential volatility in the Company's share price, 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 the Company's most recent Annual Report on Form 10-K and the Company's 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 the Company's 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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