NEWS RELEASE

bridgebio pharma reports second quarter 2023 financial results and business update

2023-08-03

- Announced consistently positive results from the Phase 3 ATTRibute-CM study of acoramidis in patients with transthyretin amyloid cardiomyopathy (ATTR-CM), including a highly statistically significant result observed on the primary endpoint with a Win Ratio of 1.8 ($p<0.0001$) and clinically meaningful and consistent separation observed on measures of mortality, morbidity, function, and quality of life; the Company intends to file a New Drug Application (NDA) for acoramidis with the U.S. Food and Drug Administration (FDA) by the end of 2023

- Presented updated six-month results from Cohort 5 of PROPEL2, a Phase 2 trial of infigratinib in children with achondroplasia, at the Endocrine Society 2023 Annual Conference (ENDO 2023), demonstrating a continued potentially best-in-class efficacy and well-tolerated safety profile, and a mean increase in annualized height velocity (AHV) of 3.38cm/year with no treatment-related adverse events

- Dosed the first participant in FORTIFY, a global Phase 3 study of BBP-418 in patients with limb girdle muscular dystrophy type 2I/R9 (LGMD2I/R9) and met with the FDA to discuss the use of glycosylated alpha-dystroglycan (αDG) levels as a surrogate endpoint; based on this meeting, the Company believes there is potential to pursue Accelerated Approval in the U.S. for BBP-418

- Shared 18-month data from the long-term extension of the Phase 2 study of encaleret in patients with autosomal dominant hypocalcemia type 1 (ADH1) at ENDO 2023, including observation of a rapid and sustained treatment effect; Phase 3 CALIBRATE registrational trial remains ongoing, with topline results expected to be announced in the first half of 2024

- Phase 1/2 trial of BBP-631 for treatment of congenital adrenal hyperplasia (CAH) continuing to progress with an update planned by the end of 2023

- Three lead KRAS programs are advancing, with an Investigational New Drug (IND) application planned for first-in-class direct $KRAS^{G12C}$ (ON) inhibitor BBO-8520 in 2023 as well as a recent selection of a clinical candidate for PI3Kα:RAS breaker with the intention to file an IND application in 2024

- Ended the quarter with $353 million in cash, cash equivalents, marketable securities, and short-term restricted cash, and $50 million of investments in equity securities, providing runway into 2H 2024

PALO ALTO, Calif., Aug. 03, 2023 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2023 and provided an update on the Company's operations.

"We'll remain ever grateful for the support of the physicians and patients in the ATTR-CM community, which helped bring the ATTRibute-CM study to its final readout," said Neil Kumar, Ph.D., founder and CEO of BridgeBio. "With these data in hand, coupled with a pipeline that could produce an additional three pivotal readouts in the next 24 months, we feel we have the ingredients to build a sustainable engine for the patients that we serve in large and small markets alike."

BridgeBio's key programs:

- Acoramidis (AG10) – Transthyretin (TTR) stabilizer for transthyretin amyloid cardiomyopathy (ATTR-CM):
    - In July 2023, the Company released topline results from ATTRibute-CM, its Phase 3 trial of acoramidis for patients with ATTR-CM. The primary endpoint analysis was highly statistically significant with a Win Ratio of 1.8 ($p<0.0001$).
    - A clinically meaningful and consistent treatment effect was observed across all measures of mortality, morbidity, function, and quality of life.
    - An on-treatment survival rate of 81% was observed, versus a placebo survival rate of 74% (absolute risk reduction of 6.43%; relative risk reduction of 25%).
    - A highly statistically significant relative risk reduction of 50% ($p<0.0001$) was observed on frequency of cardiovascular-related hospitalization.
    - In comparative exploratory post hoc analyses enabled by tafamidis drop-in, albeit at low patient numbers, acoramidis showed a 42% greater increase in serum TTR levels and a 92% improvement in median NT-proBNP relative to placebo + tafamidis.
    - Acoramidis was well-tolerated with no safety signals of potential clinical concern identified.

    - BridgeBio intends to file an NDA for acoramidis with the FDA by end of 2023 and marketing authorization applications with additional regulatory authorities globally in 2024.
    - The details of the topline results of the ATTRibute-CM trial will be presented at the annual meeting of the European Society of Cardiology, one of the premier global cardiology congresses, in Amsterdam at the end of August 2023.

- Low-dose infigratinib – FGFR1-3 inhibitor for achondroplasia and hypochondroplasia:
    - In June 2023, the Company presented updated six-month results from Cohort 5 of PROPEL2, its Phase 2 trial of infigratinib for children with achondroplasia, at ENDO 2023; the data demonstrated a significant and robust increase in annualized height velocity (AHV) with a mean change from baseline of +3.38 cm/year for 12 children.
    - 83% of children in Cohort 5 responded to infigratinib, as defined by an increase from baseline AHV of at least 25%. The mean change from baseline in AHV of responders was +4.08 cm/year.
    - Early but promising trends towards improvement in proportionality were observed, as measured by the upper and lower body segment ratio.
    - At six months, infigratinib was well-tolerated as a single daily oral therapy with no adverse events assessed as treatment-related in all patients in Cohort 5.
    - The Company has started to enroll children in the run-in for a registrational Phase 3 trial.
    - If approved, BridgeBio believes that infigratinib 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/R9 (LGMD2I/R9):
    - The Company met with the FDA to discuss the use of glycosylated αDG levels as a surrogate endpoint. Based on this meeting, the Company believes there is potential to pursue Accelerated Approval in the U.S. for BBP-418.
    - The Company has dosed the first participant in FORTIFY, its global Phase 3 study of BBP-418 in patients with LGMD2I/R9.
    - FORTIFY includes an interim analysis at 12 months focused on change in glycosylated αDG levels; topline data from this analysis is expected in late 2024/early 2025.
    - Deficiency of glycosylated αDG is the causal molecular driver of LGMD2I/R9. In the ongoing Phase 2 study, patients treated with BBP-418 had a rapid and sustained increase of glycosylated αDG levels, concurrent with sustained decreases in creatine kinase and improvements from baseline in ambulatory and clinical function measures.
    - 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/R9.

- Encaleret – Calcium-sensing receptor (CaSR) inhibitor for autosomal dominant hypocalcemia type 1 (ADH1):

    - The Company presented 18-month data from the long-term extension of its Phase 2 study of encaleret in patients with ADH1 at ENDO 2023, including observations of a rapid and sustained treatment effect. Additionally, the Company shared initial findings from its genetic testing program, highlighting that ADH1 may be the most common presentation of nonsurgical hypoparathyroidism.
    - 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, a Phase 3 registrational trial of encaleret for ADH1, 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, and the Company plans to provide an 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 application and enter the clinic in 2023.
        - A PI3Kα:RAS breaker program, investigational small molecules that are designed to block RAS-driven PI3Kα activation with a novel and potentially broad mechanism of action to target not only PI3Kα mutant tumors and RAS mutant tumors, but potentially other tumors driven by RTK activation of RAS signaling. The Company has selected a development candidate and expects to file an IND application in 2024 as the second investigational RAS cancer therapy from the BridgeBio portfolio.
        - The Company's pan-KRAS program, which targets multiple KRAS mutants including $KRAS^{G12D}$ and $KRAS^{G12V}$, 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.

Recent Corporate Updates:

- Partnership with Burjeel Holdings on project 'NADER' (Needs Assessment and Therapeutics Development for Rare Diseases – 'nader' meaning 'rare' in Arabic): Signed a preliminary, non-binding Collaboration Agreement

establishing a mutual intention to revolutionize the field of early diagnosis and treatment of rare diseases in the United Arab Emirates and the region.

- Updated encouraging clinical and biomarker data shared for the Company's Canavan disease gene therapy program: Presented promising positive data from six participants dosed in CANaspire, the Company's Phase 1/2 clinical trial of BBP-812, an investigational intravenous (IV) adeno-associated virus serotype 9 (AAV9) gene therapy for the treatment of Canavan disease. Following treatment, the N-acetylaspartate (NAA) levels of CANaspire participants were consistent with levels seen in individuals with milder Canavan disease based on findings from the Company's natural history study and reports in the scientific literature. Sustained reductions in NAA were measured in the urine, cerebrospinal fluid (CSF), and brain of all participants and have been observed for over one year in the earliest dosed participants.

Second Quarter 2023 Financial Results:

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

Cash, cash equivalents, marketable securities and short-term restricted cash, totaled $353.2 million as of June 30, 2023, compared to $466.2 million as of December 31, 2022. The net decrease of $113.0 million in cash, cash equivalents, marketable securities and short-term restricted cash is primarily attributable to net cash used in operating activities of $257.7 million, offset by net proceeds received of $144.0 million from the Follow-on public offering during the six months ended June 30, 2023.

Revenue

Revenue for the three and six months ended June 30, 2023 was $1.6 million and $3.5 million, respectively, as compared to $73.7 million and $75.4 million for the same periods in the prior year. Revenue for the three and six months ended June 30, 2023 primarily consisted of $1.5 million and $3.2 million, respectively, of services revenue under the Navire-BMS License Agreement. Revenue for the three and six months ended June 30, 2022 primarily consisted of $70.2 million of license revenue and $3.2 million of services revenue under the Navire-BMS License Agreement.

Operating Costs and Expenses

Operating costs and expenses for the three and six months ended June 30, 2023 were $147.7 million and $275.7 million, respectively, compared to $153.9 million and $329.3 million for the same periods in the prior year. The overall decrease in operating costs and expenses for the three and six months ended June 30, 2023 compared to the comparative periods was due mainly to the decreases in research, development and other (R&D) expenses resulting from the Company's reprioritization of its R&D programs; selling, general and administrative expenses

resulting from its company-wide streamlining of costs; and restructuring, impairment and related charges since the majority of the restructuring initiatives commenced in the first quarter of 2022. The effects of the Company's restructuring initiative which commenced in the first quarter of 2022, continue to be realized due to the Company's reductions in operating costs and expenses. Restructuring, impairment and related charges for the three and six months ended June 30, 2023, amounted to $3.5 million and $6.9 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 $8.4 million and $31.1 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. The Company remains committed to evaluating various restructuring alternatives aimed at driving operational changes in business processes. These alternatives includes enhancing commercialization efforts, improving efficiencies, and achieving cost savings.

Stock-based compensation expenses included in operating costs and expenses for the three months ended June 30, 2023 were $27.2 million, of which $13.2 million is included in research, development and other (R&D) expenses, $14.0 million is included in selling, general and administrative expenses. Stock-based compensation expenses included in operating costs and expenses for the three months ended June 30, 2022 were $28.3 million, of which $14.3 million is included in research, development and other (R&D) expenses, and $14.0 million is included in selling, general and administrative expenses.

Stock-based compensation expenses included in operating costs and expenses for the six months ended June 30, 2023 were $50.7 million, of which $25.0 million is included in research, development and other (R&D) expenses, $25.7 million is included in selling, general and administrative expenses. Stock-based compensation expenses included in operating costs and expenses for the six months ended June 30, 2022 were $52.6 million, of which $22.9 million is included in research, development and other (R&D) expenses, $28.5 million is included in selling, general and administrative expenses, and $1.2 million is included in restructuring, impairment and related charges.

“Following the recent announcement and strength of our Phase 3 ATTRibute-CM data, we will continue to explore multiple options to fully resource the acoramidis launch while optimizing cost of capital, including partnerships, royalty transactions, and equity financing,” said Brian Stephenson, Ph.D., CFA, Chief Financial Officer of BridgeBio. “We anticipate $300-$350 million of investment will support acoramidis from here through the first 12 months of commercial launch. This coupled with our slate of pivotal readouts over the next 24 months offers the opportunity for meaningful value creation for both patients and investors.”

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,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenue	$ 1,641	$ 73,746	$ 3,467	$ 75,440
Operating costs and expenses:				
Research, development and others	108,087	109,100	201,599	218,097
Selling, general and administrative	36,122	36,426	67,230	80,139
Restructuring, impairment and related charges	3,531	8,396	6,900	31,058
Total operating costs and expenses	147,740	153,922	275,729	329,294
Loss from operations	(146,099)	(80,176)	(272,262)	(253,854)
Other income (expense), net:				
Interest income	4,514	766	8,667	1,033
Interest expense	(20,594)	(20,279)	(40,715)	(40,623)
Gain from sale of priority review voucher, net	—	107,946	—	107,946
Other income (expense), net	1,476	(10,816)	875	(18,391)
Total other income (expense), net	(14,604)	77,617	(31,173)	49,965
Net loss	(160,703)	(2,559)	(303,435)	(203,889)
Net loss (income) attributable to redeemable convertible noncontrolling interests and noncontrolling interests	2,804	(7,297)	5,380	(2,364)
Net loss attributable to common stockholders of BridgeBio	$ (157,899)	$ (9,856)	$ (298,055)	$ (206,253)
Net loss per share, basic and diluted	$ (0.98)	$ (0.07)	$ (1.90)	$ (1.41)
Weighted-average shares used in computing net loss per share, basic and diluted	160,535,435	146,684,804	156,645,838	146,285,694

Stock-based Compensation	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Research, development and others	$ 13,229	$ 14,352	$ 25,008	$ 22,909
Selling, general and administrative	13,947	13,953	25,645	28,505
Restructuring, impairment and related charges	—	—	—	1,172
Total stock-based compensation	$ 27,176	$ 28,305	$ 50,653	$ 52,586

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

	June 30, 2023	December 31, 2022
	(Unaudited)	(1)
Assets		
Cash and cash equivalents and marketable securities	$ 333,307	$ 428,269
Investment in equity securities	50,487	43,653
Receivable from licensing and collaboration agreements	8,614	17,079
Short-term restricted cash	19,930	37,930
Prepaid expenses and other current assets	20,546	21,922
Property and equipment, net	13,047	14,569
Operating lease right-of-use assets	9,814	10,678
Intangible assets, net	27,515	28,712
Other assets	20,401	20,224
Total assets	$ 503,661	$ 623,036
Liabilities, Redeemable Convertible Noncontrolling Interests and Stockholders' Deficit		
Accounts payable	$ 3,874	$ 11,558

Accrued and other liabilities	102,470	106,195
Operating lease liabilities	14,692	15,949
2029 Notes	735,940	734,988
2027 Notes	542,501	541,634
Term loan	440,496	430,993
Other long-term liabilities	13,326	26,643
Redeemable convertible noncontrolling interests	333	(1,589)
Total BridgeBio stockholders' deficit	(1,362,023)	(1,254,617)
Noncontrolling interests	12,052	11,282
Total liabilities, redeemable convertible noncontrolling interests and stockholders' deficit	$ 503,661	$ 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)

	Six Months Ended June 30,	
	2023	2022
Operating activities:		
Net loss	$ (303,435)	$ (203,889)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	49,085	52,409
Depreciation and amortization	3,270	3,466
Noncash lease expense	2,024	2,889
Accrual of payment-in-kind interest on term loan	6,742	—
Loss on deconsolidation of PellePharm	1,241	—
(Gain) loss from investment in equity securities, net	(2,399)	23,228
Fair value of shares issued under a license agreement	—	4,567
Accretion of debt	4,580	4,383
Fair value adjustment of warrants	(222)	1,390
Loss on sale of certain assets	—	6,261
Impairment of long-lived assets	—	12,653
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	(328)	853
Changes in operating assets and liabilities:		
Receivable from licensing and collaboration agreements	8,466	2,993
Prepaid expenses and other current assets	1,057	(3,021)
Other assets	32	8,691
Accounts payable	(4,098)	(3,090)
Accrued compensation and benefits	(11,071)	(9,402)
Accrued research and development liabilities	(11,322)	5,953
Operating lease liabilities	(2,443)	(3,348)
Deferred revenue	(3,184)	16,641
Accrued professional and other liabilities	4,330	7,785
Net cash used in operating activities	(257,675)	(191,088)
Investing activities:		
Purchases of marketable securities	(19,754)	(119,611)
Maturities of marketable securities	41,550	293,919
Purchases of investment in equity securities	(71,504)	(10,930)
Sales of investment in equity securities	67,068	9,708
Decrease in cash and cash equivalents resulting from deconsolidation of PellePharm	(503)	—
Payment for an 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	(440)	(3,261)

Net cash provided by investing activities	16,417	288,325
Financing activities:		
Proceeds from issuance of common stock through Follow-on offering, net	144,049	—
Repayment of term loan	—	(20,486)
Proceeds from BridgeBio common stock issuances under ESPP	1,809	966
Repurchase of shares to satisfy tax withholding	(1,715)	(476)
Issuance costs associated with term loan	—	(1,120)
Proceeds from stock option exercises, net of repurchases	312	160
Other financing activities	4,563	—
Net cash provided by (used in) financing activities	149,018	(20,956)
Net (decrease) increase in cash, cash equivalents and restricted cash	(92,240)	76,281
Cash, cash equivalents and restricted cash at beginning of period	416,884	396,365
Cash, cash equivalents and restricted cash at end of period	$ 324,644	$ 472,646

	Six Months Ended June 30,	
	2023	2022
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	$ 28,738	$ 25,435
Supplemental Disclosures of Noncash Investing and Financing Information:		
Payment-in-kind interest added to principal of term loan	$ —	$ 5,075
Unpaid property and equipment	$ 131	$ 73
Transfers (to) from noncontrolling interests	$ (5,940)	$ 1,456
Reconciliation of Cash, Cash Equivalents and Restricted Cash:		
Cash and cash equivalents	$ 302,438	$ 470,098
Short-term restricted cash	19,930	—
Restricted cash — Included in “Prepaid expenses and other current assets”	—	140
Restricted cash — Included in “Other assets”	2,276	2,408
Total cash, cash equivalents and restricted cash at end of period shown in the condensed consolidated statements of cash flows	$ 324,644	$ 472,646

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, market potential of our programs and product candidates, including the statement in Dr. Kumar’s quote regarding our data, pipeline and potential product launches; the timing and success of our clinical development programs, including the progress of our ongoing and planned clinical trials of acoramidis for patients with ATTR-CM, our plans to file a new NDA for acoramidis with the FDA by end of year 2023, our planned marketing authorization applications with additional regulatory authorities in 2024, the planned presentation of the details of the topline results of ATTRibute-CM trial at the annual meeting of the European Society of Cardiology, and the availability of data from our clinical trials of acoramidis; the availability of data from our clinical trials of for BBP-418 in LGMD2I/R9, the potential and the opportunity to pursue Accelerated Approval Pathway for BBP-418 in LGMD2I/R9 in the U.S., 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 Company’s finding that ADH1 may be the most common presentation of nonsurgical hypoparathyroidism, the timing and status of Phase 3 CALIBRATE registrational trial of encaleret for ADH1, the timing of announcement of topline data from CALIBRATE in the first half of 2024, and the success of encaleret (if approved), including its potential to be the first therapy specifically indicated for the treatment of ADH1; the continuation and progress of our ongoing Phase 1/2 trial of BBP-631 for CAH, with a planned update by the end of 2023; the continued development, the timing, progression and success of the RAS franchise, including an IND application planned for first-in-class direct $KRAS^{G12C}$ (ON) inhibitor BBO-8520 in 2023, the intention to file an IND for a selected development candidate for PI3Kα:RAS breaker in 2024 as the second RAS cancer therapy from the BridgeBio portfolio, and the planned development candidate selection for the pan-KRAS program, for late 2023 or early 2024; our anticipated cash runway; the anticipated amounts needed to support our planned operations, including the potential commercial launch of acoramidis, and potential sources and availability of additional capital, 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 or through potential partnerships, royalty transactions and equity financings, 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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