Zogenix Provides Corporate Update and Reports Fourth Quarter and Full-Year 2021 Financial Results

February 28, 2022

- *Total revenue of $26.6 million in the fourth quarter and $81.7 million for the full year*
- *FINTEPLA® net product sales of $23.5 million in the fourth quarter and $74.7 million for the full year*
- *Announced U.S. Food and Drug Administration acceptance with Priority Review of Supplemental New Drug Application for FINTEPLA in Lennox-Gastaut Syndrome (LGS)*
- *Submitted Type II Variation Application to the European Medicines Agency to expand the use of FINTEPLA for LGS*
- *Submitted New Drug Application to Japan's Ministry of Health, Labour & Welfare for the marketing approval of FINTEPLA in Dravet syndrome*
- *Previously announced agreement to be acquired by UCB; transaction expected to close in the first half of 2022*

EMERYVILLE, Calif., Feb. 28, 2022 (GLOBE NEWSWIRE) -- Zogenix (NASDAQ: ZGNX), a global biopharmaceutical company developing and rare disease therapies, today provided a corporate update and announced financial results for the fourth quarter and full-year ended December 31, 2021.

"The year 2021 represented a transformational period for Zogenix, with our ongoing successful commercial launches of FINTEPLA® in the U.S. and Europe, and significant regulatory progress and advancement of our late-stage development programs. In the past quarter, we announced U.S. Food and Drug Administration (FDA) acceptance of the supplemental New Drug Application (sNDA), a submission of a Type II variation application for FINTEPLA in Europe to potentially expand authorized use of FINTEPLA in a second indication, Lennox-Gastaut syndrome (LGS), as well as a J-NDA submission for FINTEPLA in Dravet syndrome in Japan. The recently announced acquisition by UCB will accelerate our mission to serve rare disease patients globally and deliver innovative therapies to additional patients and families in need," said Stephen J. Farr, Ph.D., President and CEO of Zogenix.

Corporate Update

- FINTEPLA for the treatment of seizures associated with Dravet syndrome:
  - As of December 31, 2021, the total number of unique prescribers was 375 and 1,129 patients were prescribed FINTEPLA and referred to the REMS program in the U.S.
  - European commercial launches in Germany and France continue momentum with increasing adoption of FINTEPLA among prescribers and patients
  - Zogenix Access Program is now providing FINTEPLA to patients in 9 countries where the therapy is not yet commercially reimbursed as the company pursues country-by-country reimbursement in Europe
  - Announced submission of a J-NDA to the Japanese Ministry of Health, Labour & Welfare
  - Presented new safety and efficacy data for FINTEPLA in eight abstracts at the American Epilepsy Society Annual Meeting
- FINTEPLA for the treatment of seizures associated with LGS:
  - Announced FDA acceptance with Priority Review of sNDA for FINTEPLA in LGS. PDUFA target action date is March 25th, 2022
  - Submitted Type II variation application to European Medicines Agency (EMA) for approval in LGS
- FINTEPLA for the treatment of seizures associated with CDKL5 Deficiency Disorder (CDD):
  - Based on a positive meeting with FDA, a single Phase 3 study, if successful, could be sufficient to support an sNDA submission
  - Targeting enrollment of first patient in global Phase 3 study in Q1 2022
- MT1621 for the treatment of thymidine kinase 2 (TK2) deficiency:
  - Scientific Advice from EMA supportive of marketing authorization for the treatment of patients with age of TK2d

symptom onset < 12 years old

- Ongoing studies continue to proceed as planned to support potential NDA submission in the second half of 2022
- Announced support of a no-cost genetic testing program, the United Mitochondrial Disease Foundation (UMDF) Pilot Genetic Testing Project, in partnership with UMDF and Probably Genetic, to help patients obtain a confirmed genetic diagnosis of mitochondrial disease

- UCB Acquisition of Zogenix:
  - On January 19, 2022, UCB and Zogenix announced that the companies have entered into a definitive agreement under which UCB would acquire Zogenix, Inc. Under the terms of the agreement, UCB commenced a tender offer to purchase all outstanding shares of Zogenix for a purchase price per share of US$ 26.00 in cash at closing, plus a contingent value right (CVR) for a potential cash payment of US$ 2.00 upon EU approval by December 31, 2023, of FINTEPLA as an orphan medicine for treatment of LGS. The upfront consideration represented a 72% premium to Zogenix shares based on the 30-day volume weighted average closing stock price of Zogenix prior to signing. The total transaction is valued at up to approximately US$ 1.9 billion / € 1.7 billion. The transaction is subject to regulatory approvals and other customary closing conditions and is expected to close in the first half of 2022.

Fourth Quarter 2021 Financial Results

- The Company recorded $26.6 million in revenue for the fourth quarter ended December 31, 2021. This included total net product sales of FINTEPLA of $23.5 million, in addition to $3.1 million in revenue as a result of the March 2019 collaboration with Nippon Shinyaku Co., Ltd. for FINTEPLA in Dravet syndrome and LGS in Japan. Zogenix recorded $8.5 million in revenue for the corresponding period of 2020.
- Research and development expenses for the fourth quarter ended December 31, 2021, totaled $41.8 million, compared to $36.0 million in the fourth quarter ended December 31, 2020.
- Selling, general and administrative expenses for the fourth quarter ended December 31, 2021, totaled $43.8 million, up from $29.2 million in the fourth quarter ended December 31, 2020. The increase was driven by ongoing Fintepla launch activities in Dravet syndrome in the U.S. and Europe and preparations for potential launches for FINTEPLA in LGS.
- Net loss for the fourth quarter ended December 31, 2020, was $54.9 million, or a net loss of $0.98 per share, compared with a net loss of $70.2 million, or a net loss of $1.26 per share, in the fourth quarter ended December 31, 2020.

Year Ended December 31, 2021 Financial Results Compared to Year Ended December 31, 2020

- The Company recorded $81.7 million in revenue for the year ended December 31, 2021. This included total net product sales of FINTEPLA of $74.7 million, in addition to $7.0 million in revenue as a result of the March 2019 collaboration with Nippon Shinyaku Co., Ltd. for FINTEPLA in Dravet syndrome and LGS in Japan. Zogenix recorded in $13.6 million revenue for the corresponding period of 2020.
- Research and development expenses for the year ended December 31, 2021, totaled $142.7 million, up from $138.0 million in the year ended December 31, 2020.
- Selling, general and administrative expenses for the year ended December 31, 2021, totaled $148.5 million, up from $99.6 million in the year ended December 31, 2020, as the Company continued investment related to the launch of FINTEPLA for the treatment of Dravet syndrome in the U.S. and Europe and preparations for a potential launch for FINTEPLA in LGS.
- Net loss for the year ended December 31, 2021, was $227.4 million, or a net loss of $4.07 per share, compared with a net loss of $209.4 million, or a net loss of $3.90 per share, in the year ended December 31, 2020.
- As of December 31, 2021, the Company had $301.7 million in cash, cash equivalents, and marketable securities, compared to $505.1 million at December 31, 2020

Conference Call/Earnings Materials

Given the recently announced agreement for Zogenix to be acquired by UCB, Zogenix will not be hosting a conference call. Earnings materials are available publicly on the Investor Relations page of our website at http://zogenix.com. Questions may be directed to the Investor Relations team via the contact information below.

Additional Information and Where to Find It

This communication is not an offer to buy nor a solicitation of an offer to sell any securities of Zogenix, Inc. (the "Company"). The solicitation and the offer to buy shares of the Company's common stock is being made pursuant to a tender offer statement on Schedule TO, including an offer to purchase, a letter of transmittal and other related materials that was filed by UCB S.A. (the "Parent") and Zinc Merger Sub, Inc. ("Merger Sub") with the Securities and Exchange Commission ("SEC") on February 1, 2022. In addition, the Company has filed a Solicitation/Recommendation Statement on Schedule 14D-9 with respect to the tender offer with the SEC on February 1, 2022. Investors can obtain a free copy of these materials and other documents filed by Parent, Merger Sub and the Company with the SEC at the website maintained by the SEC at www.sec.gov. Investors may also obtain, at no charge, any such documents filed or furnished to the SEC by the Company under the "Investors" section of the Company's website at www.zogenix.com. INVESTORS AND SECURITY HOLDERS ARE ADVISED TO READ THESE DOCUMENTS, INCLUDING THE SOLICITATION/RECOMMENDATION STATEMENT OF THE COMPANY AND ANY AMENDMENTS THERETO, AS WELL AS ANY OTHER DOCUMENTS RELATING TO THE TENDER OFFER AND THE MERGER THAT ARE FILED WITH THE SEC, CAREFULLY AND IN THEIR ENTIRETY PRIOR TO MAKING ANY DECISIONS WITH RESPECT TO WHETHER TO TENDER THEIR SHARES INTO THE TENDER OFFER BECAUSE THEY CONTAIN IMPORTANT INFORMATION, INCLUDING THE TERMS AND CONDITIONS OF THE TENDER OFFER.

About Zogenix

Zogenix is a global biopharmaceutical company committed to developing and commercializing therapies with the potential to transform the lives of patients and their families living with rare diseases. The company's first rare disease therapy, FINTEPLA® (fenfluramine) oral solution, has been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency and is under regulatory review in Japan for the treatment of seizures associated with Dravet syndrome, a rare, severe lifelong epilepsy. The U.S. FDA recently accepted for filing Zogenix's supplemental New Drug Application (sNDA) and granted Priority Review for the use of FINTEPLA for the treatment of seizures associated with an additional rare epilepsy, Lennox-Gastaut syndrome (LGS). Zogenix is also initiating a study of FINTEPLA in a genetic epilepsy called CDKL5 Deficiency Disorder (CDD) and is collaborating with Tevard Biosciences to identify and develop potential next-generation gene therapies for Dravet syndrome and other genetic epilepsies. The company has an additional late-stage development program, MT-1621, in a mitochondrial disease called TK2 deficiency.

Forward-Looking Statements

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed," and similar expressions are intended to identify forward-looking statements. These statements include: the timing and ability of Zogenix to complete regulatory submission in the EU and Japan for its product candidates; the expected timing of reporting data from clinical trials; the expected timing of review of Zogenix's regulatory submissions including the sNDA for the treatment of seizures associated with LGS; Zogenix's commercialization plans in the U.S. and Europe; and Zogenix's plans with respect to its development programs. These statements are based on Zogenix's current beliefs and expectations. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in Zogenix's business, including, without limitation: FINTEPLA may not achieve broad market acceptance as a treatment option of seizures associated with LGS or Dravet syndrome which would limit Zogenix's ability to general revenues; Zogenix may not be successful in executing its sales and marketing strategy for the commercialization of FINTEPLA in the U.S. and Europe, including due to the costs and procedures related to the REMS certification process or controlled access program; the structure, timing and completion of the announced merger between us and UCB S.A., and any effects of the announcement, pendency or completion of the announced merger, including the anticipated benefits therefrom; the COVID-19 pandemic may continue to disrupt Zogenix's business operations, impairing the ability to commercialize FINTEPLA in the U.S. and Europe and Zogenix's ability to generate product revenue in the U.S. and Europe and conduct its development programs; unexpected adverse side effects or inadequate therapeutic efficacy of fenfluramine that could limit regulatory approval or commercialization, or that could result in recalls or product liability claims; later developments with FDA that may be inconsistent with the already completed meetings; additional data from Zogenix's ongoing studies may contradict or undermine the data previously reported; the potential for the FDA to delay timing of review of the sNDA due to the FDA's internal resource constraints or other reasons; and other risks described in Zogenix's prior press releases as well as in public periodic filings with the U.S. Securities & Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

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ZOGENIX INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands)	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 101,180	$ 166,916
Marketable securities	200,535	338,193
Accounts receivable, net	10,139	3,824
Inventory	5,492	1,026
Prepaid expenses	12,487	7,279
Other current assets	24,735	4,936
Total current assets	354,568	522,174
Property and equipment, net	7,197	8,724
Operating lease right-of-use assets	6,605	7,748
Intangible asset, net	90,673	98,558
Goodwill	6,234	6,234
Other non-current assets	3,212	7,692
Total assets	$ 468,489	$ 651,130
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 21,998	$ 11,945
Accrued and other current liabilities	55,413	54,964
Deferred revenue, current	5,089	5,318
Current portion of operating lease liabilities	1,694	1,688
Current portion of contingent consideration	13,500	8,800
Total current liabilities	97,694	82,715
Deferred revenue, non-current	3,257	5,479
Operating lease liabilities, net of current portion	8,617	10,314
Contingent consideration, net of current portion	21,785	33,600
Convertible debt	158,165	149,353
Total liabilities	289,518	281,461
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	56	56
Additional paid-in capital	1,731,153	1,694,524
Accumulated other comprehensive loss	15	(71)
Accumulated deficit	(1,552,253)	(1,324,840)

Total stockholders' equity	178,971	369,669
Total liabilities and stockholders' equity	$ 468,489	$ 651,130

ZOGENIX INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(in thousands, except per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Net product sales	$ 23,471	$ 8,067	$ 74,740	$ 9,587
Collaboration revenue	3,137	435	6,950	4,056
Total revenues	26,608	8,502	81,690	13,643
Costs and expenses:				
Cost of product sales (excluding amortization of intangible asset)	1,642	402	4,834	542
Research and development	41,791	35,964	142,659	138,002
Selling, general and administrative	43,811	29,242	148,524	99,574
Intangible asset amortization	1,971	1,971	7,885	3,942
Acquired in-process research and development costs	—	6,200	—	10,700
Change in fair value of contingent	385	2,500	1,885	8,600
Total costs and expenses	89,600	76,279	305,787	261,360
Loss from operations	(62,992)	(67,777)	(224,097)	(247,717)
Other income (expense), net:				
Interest income	80	387	659	2,891
Interest expense	(3,903)	(3,759)	(15,276)	(3,759)
Other income, net	12,037	979	11,406	21,777
Total other income (expense), net	8,214	(2,393)	(3,211)	20,909
Loss before income taxes	(54,778)	(70,170)	(227,308)	(226,808)
Income tax expense (benefit)	105	—	105	(17,425)
Net loss	$ (54,883)	$ (70,170)	$ (227,413)	$ (209,383)
Net loss per share, basic and diluted	$ (0.98)	$ (1.26)	$ (4.07)	$ (3.90)

ZOGENIX

Source: Zogenix, Inc