# Zogenix Provides Corporate Update and Reports Fourth Quarter and Full-Year 2018 Financial Results

February 28, 2019

- ***Completed rolling submission of an NDA to the U.S. FDA and an MAA to the EMA for FINTEPLA® for the treatment of seizures associated with Dravet syndrome in February 2019***
  ***-- EMA has accepted MAA for review; outcome of the MAA review by the EMA expected in Q1 2020***
  ***-- Notice regarding FDA acceptance of NDA filing and notification of PDUFA target date expected in next several weeks***

- ***Continued to advance enrollment of global Phase 3 trial of FINTEPLA for the treatment of Lennox-Gastaut syndrome (Study 1601)***

- ***Presented data from nine abstracts, including four "late-breakers," at the 2018 AES Annual Meeting***

- ***Concluded full-year 2018 with $514.2 million in cash, cash equivalents, and marketable securities***

EMERYVILLE, Calif., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Zogenix, Inc. (NASDAQ: ZGNX), a global pharmaceutical company developing rare disease therapies, today provided a corporate update and announced financial results for the fourth quarter and full-year ended December 31, 2018.

"We are pleased that our recently submitted Marketing Authorization Application (MAA) for FINTEPLA® for the treatment of seizures associated with Dravet syndrome, an often-catastrophic epileptic encephalopathy that begins in infancy, has been accepted by the European Medicines Agency (EMA)," said Stephen J. Farr, Ph.D., President and CEO of Zogenix. "We expect an outcome of the MAA review by the EMA in the first quarter of 2020. We are awaiting a filing status and a potential Prescription Drug User Fee Act (PDUFA) target date from the U.S. Food & Drug Administration (FDA) following completion of our rolling submission of a New Drug Application (NDA) for FINTEPLA in early February this year. We remain focused on preparing for the potential launch of FINTEPLA in the U.S. and Europe and have achieved meaningful progress in building and expanding our commercial organization in recent months."

"Recruitment continues to progress well in our ongoing global Phase 3 trial (Study 1601) of FINTEPLA for the treatment of Lennox-Gastaut syndrome (LGS), another difficult-to-treat childhood-onset epileptic encephalopathy. The study now includes a significant number of European sites, which either have been activated or will shortly open during this quarter. We expect to complete enrollment in Study 1601 later this year and report top-line results in the first quarter of 2020. In addition, we anticipate initiating a randomized placebo-controlled trial in Doose syndrome, another severe and often treatment-resistant childhood epilepsy, in the second half of 2019.

"Importantly, our business is supported by an extremely strong balance sheet, as we ended 2018 with $514.2 million in cash, cash equivalents, and marketable securities," concluded Dr. Farr.

**Corporate Update**

- Completed the rolling submission of an NDA to the U.S. FDA and submitted an MAA to the EMA for FINTEPLA in February 2019, both for the treatment of seizures associated with Dravet syndrome.
  -- EMA has accepted the MAA for review; outcome of regulatory review anticipated in the first quarter of 2020.
  -- Zogenix expects to receive notice from the FDA regarding NDA acceptance for filing and a PDUFA target date in the next several weeks.

- Continued U.S. and European commercial preparations for FINTEPLA. The Company is preparing for a U.S. commercial launch shortly following potential NDA approval.

- Continued enrollment in global Phase 3 trial of FINTEPLA for treatment of seizures associated with LGS (Study 1601).

- Presented data from nine abstracts, including four "late-breakers," at the 2018 American Epilepsy Society Annual Meeting.
  -- Data from second pivotal Phase 3 trial (Study 1504) consistent with results of first pivotal Phase 3 trial (Study 1) in showing highly significant convulsive seizure reduction for FINTEPLA versus placebo.
  -- Clinically meaningful reduction in convulsive seizure frequency for FINTEPLA maintained over Phase 3 open-label extension trial (Study 1503).
  -- Positive findings on the impact of treatment with FINTEPLA on everyday executive function in patients with Dravet syndrome.

- Concluded year ended December 31, 2018, with $514.2 million in cash, cash equivalents, and marketable securities.

**Fourth Quarter 2018 Financial Results**

- Research and development expenses for the fourth quarter ended December 31, 2018, totaled $23.6 million, up from $18.1 million in the fourth quarter ended December 31, 2017, as the Company expanded clinical trial activities related to its ongoing Phase 3 development programs of FINTEPLA in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the fourth quarter ended December 31, 2018, totaled $11.3 million, compared with $7.8 million in the fourth quarter ended December 31, 2017.

- Net loss for the fourth quarter ended December 31, 2018, was $22.4 million, or a net loss of $0.53 per share, compared with a net loss of $39.7 million, or a net loss of $1.17 per share in the fourth quarter ended December 31, 2017.

**Year Ended December 31, 2018, Financial Results Compared to Year Ended December 31, 2017**

- Due to the wind-down of Sumavel DosePro manufacturing operations in September 2017, the Company recorded no revenue for the year-ended December 31, 2018. This compares with total revenue of $9.8 million in the year ended December 31, 2017, consisting entirely of contract manufacturing revenue for Sumavel DosePro.

- Research and development expenses for the 12 months ended December 31, 2018, totaled $101 million, up from $67.4 million in the 12 months ended December 31, 2017, as the Company expanded clinical trial activities related to its ongoing Phase 3 development programs of FINTEPLA in Dravet syndrome and LGS.

- Selling, general and administrative expenses for the 12 months ended December 31, 2018, were $39.0 million, compared with $25.9 million in the 12 months ended December 31, 2017.

- Net loss for the 12 months ended December 31, 2018, was $123.9 million, or a net loss of $3.27 per share, compared with a net loss of $126.8 million, or a net loss of $4.65 per share in the 12-months December 31, 2017.

- As of December 31, 2018, the Company had $514.2 million in cash, cash equivalents, and marketable securities, compared to $293.5 million at December 31, 2017.

**Conference Call**

***Thursday, February 28 @ 4:30 PM Eastern Time/1:30 PM Pacific Time***

| | |
|---|---|
| Toll Free: | 877-407-9716 |
| International: | 201-493-6779 |
| Conference ID: | 13687457 |
| Webcast: | http://public.viavid.com/index.php?id=133233 |

*Replays available through March 14:*

| | |
|---|---|
| Domestic: | 844-512-2921 |
| International: | 412-317-6671 |
| Replay PIN: | 13687457 |

**About Zogenix**

Zogenix is a global pharmaceutical company committed to developing and commercializing transformative therapies to improve the lives of patients and their families living with rare diseases. For more information, visit www.zogenix.com.

**Forward Looking Statement**

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

potential timing of acceptance and approval, if any, by the FDA and the EMA of the NDA and MAA, respectively, for FINTEPLA; Zogenix's plans regarding the development of FINTEPLA in Lennox-Gastaut syndrome; the need for FINTEPLA to address unmet medical need; and the patient population. 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: the FDA may disagree that the existing safety and efficacy data is sufficient to allow an NDA review and approval, the FDA may not agree with Zogenix's interpretation of the results of the clinical trials of FINTEPLA; additional data from Zogenix's ongoing studies may contradict or undermine the data submitted in the NDA for FINTEPLA; the uncertainties associated with the clinical development and regulatory approval of product candidates such as FINTEPLA; unexpected adverse side effects or inadequate therapeutic efficacy of FINTEPLA that could limit approval and/or commercialization, or that could result in recalls or product liability claims; 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, except par value)

| | December 31, | |
|---|---|---|
| | **2018** | **2017** |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 68,454 | $ 293,503 |
| Marketable securities | 445,733 | — |
| Prepaid expenses | 6,718 | 5,994 |
| Other current assets | 11,825 | 5,206 |
| Total current assets | 532,730 | 304,703 |
| Property and equipment, net | 2,870 | 245 |
| Intangible assets | 102,500 | 102,500 |
| Goodwill | 6,234 | 6,234 |
| Other assets | 3,997 | 3,931 |
| Total assets | $ 648,331 | $ 417,613 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $ 7,989 | $ 3,356 |
| Accrued clinical trial expenses | 10,621 | 8,657 |

| | | |
|---|---|---|
| Accrued compensation | 5,277 | 6,616 |
| Other accrued liabilities | 1,845 | 1,842 |
| Current portion of contingent consideration | 32,300 | — |
| Common stock warrant liabilities | 343 | 512 |
| Total current liabilities | 58,375 | 20,983 |
| Contingent consideration | 45,900 | 76,900 |
| Deferred income taxes | 17,425 | 17,425 |
| Other long-term liabilities | 3,830 | 784 |
| Total liabilities | 125,530 | 116,092 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock | — | — |
| Common stock | 42 | 35 |
| Additional paid-in capital | 1,218,710 | 873,526 |
| Accumulated deficit | (695,954) | (572,040) |
| Accumulated other comprehensive loss | 3 | — |
| Total stockholders' equity | 522,801 | 301,521 |
| Total liabilities and stockholders' equity | $ 648,331 | $ 417,613 |

**Zogenix, Inc.**
**Condensed Consolidated Statements of Operations (Unaudited)**
(in thousands, except per share amounts)

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Contract manufacturing revenue | $ — | $ — | $ — | $ 9,821 |
| Costs and expenses: | | | | |
| Cost of contract manufacturing | — | — | — | 10,729 |
| Research and development | 23,596 | 18,080 | 100,925 | 67,449 |
| Selling, general and administrative | 11,287 | 7,756 | 38,950 | 25,885 |
| Loss on contract termination | — | — | — | 478 |
| Change in fair value of contingent consideration | (1,900) | 12,500 | 1,300 | 24,100 |
| Asset impairment charges | — | — | — | 1,116 |
| Total costs and expenses | 32,983 | 38,336 | 141,175 | 129,757 |
| Loss from operations | (32,983) | (38,336) | (141,175) | (119,936) |
| Other income (expense): | | | | |
| Interest income | 3,175 | 758 | 7,170 | 1,090 |
| Interest expense | — | (579) | (6) | (2,644) |
| Loss on extinguishment of debt | — | (1,498) | — | (4,876) |
| Change in fair value of common stock warrant liabilities | 264 | (63) | 169 | 297 |
| Other (expense) income, net | 7,111 | (24) | 10,126 | 47 |
| Total other income (expense) | 10,550 | (1,406) | 17,459 | (6,086) |
| Loss from continuing operations before income taxes | (22,433) | (39,742) | (123,716 | (126,022) |
| Income tax benefit | - | (41) | | — |
| Net loss from continuing operations | (22,433) | (39,783) | (123,716) | (126,022) |
| Net loss (income) from discontinued operations, net of taxes | — | 75 | (198) | (795) |
| Net Loss | $ (22,433) | $ (39,708) | $ (123,914 | $ (126,817) |
| Net loss per share, basic and diluted | $ (0.53) | $ (1.17) | $ (3.27) | $ (4.65) |


Source: Zogenix, Inc.