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EirGenix, Inc. | 6589.TWO

EirGenix

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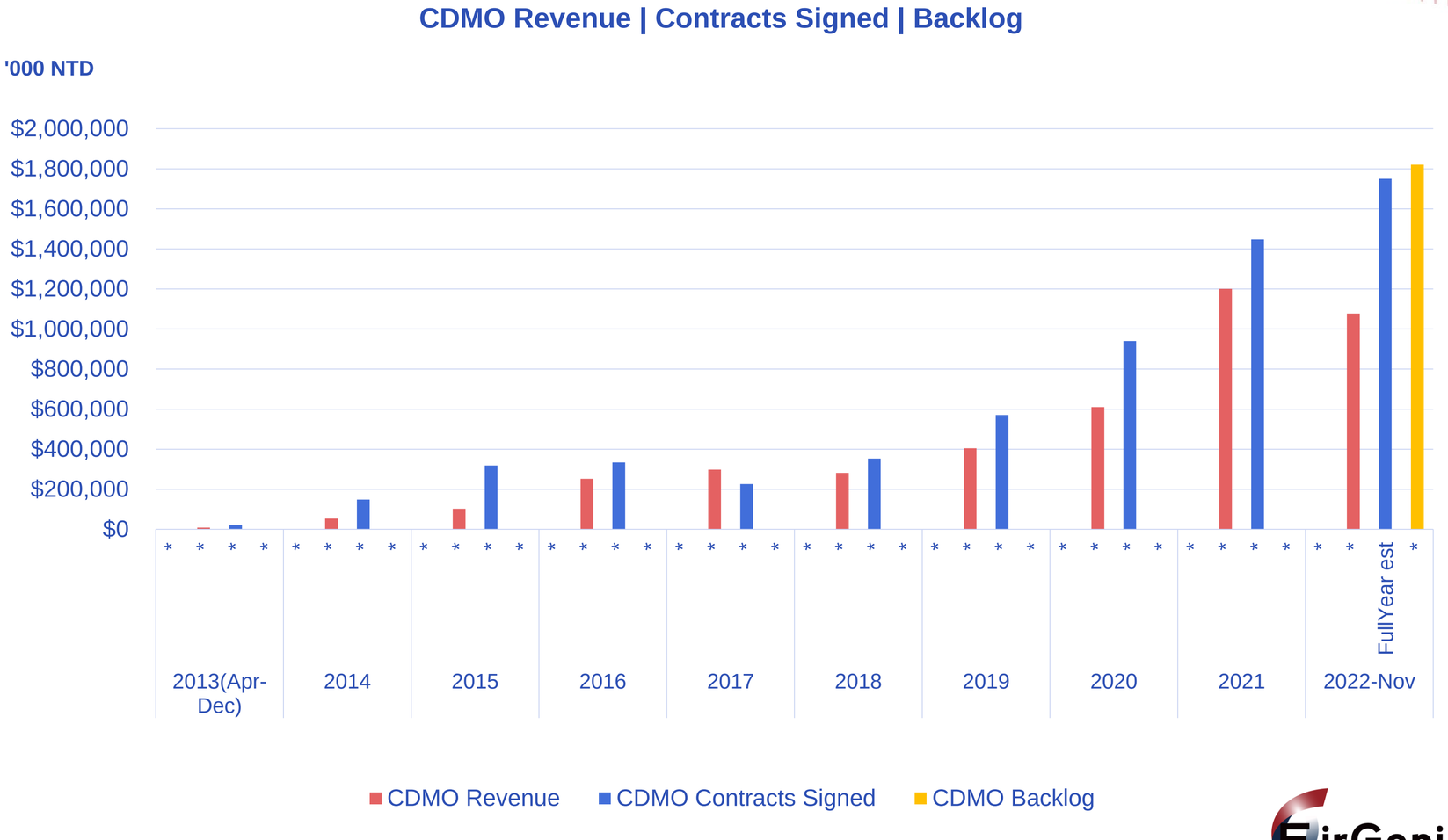
CDMO Business

Newly Signed Contracts Continue To Grow

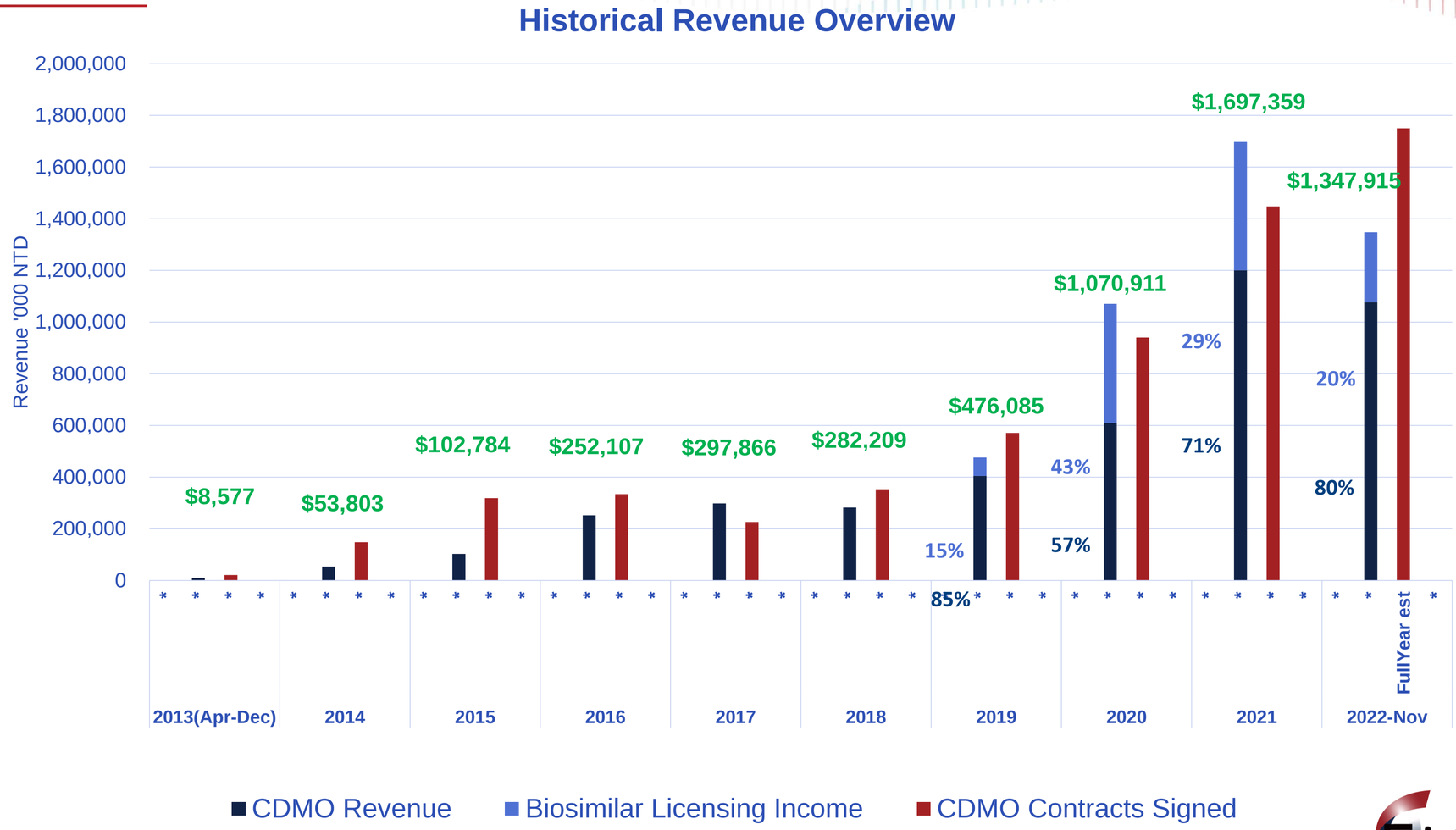
- 2022 Full year CDMO newly signed contracts exceeding NT$1.75bn, grew over 20%YoY
- Order backlog over NT$1.8bn, and expecting to complete over the next two years
- Average CDMO projects backlog 1.5 to 2 years



Overall Revenue Growth Trend

Revenue Contribution From Both CDMO & Product Licensing

- 2022 Full year revenue likely to slight decline YoY due to, 1) Product licensing milestone delay to 2023, 2) CDMO operation held back due to Xizhi facility renovation for nearly four months
- Expect 2023 revenue growth moment to regain, after executing the licensing approval milestones, and CDMO contracts/proejcts continue to grow



EG12014

Trastuzumab Biosimilar - EG12014 (HERWENDA® - Sandoz | EIRGASUN® - EirGenix)

| 2019-Apr, Signed global licensing (excluding Taiwan, Mainland China, Japan, S. Korea and Russia) agreement with Sandoz AG for the upfront and milestone payment of USD 70 million, plus the profit sharing of the future global sales. EirGenix will be in charge of the product manufacturing。Currently the market licensing applications submitted for US, EU and Taiwan.

| US FDA Drug Licensing Application

- 2021/12/18 EirGenix's global (excluding Taiwan, Mainland China, Japan, South Korea and Russia) marketing partner, Sandoz submitted BLA to US FDA, and received official acceptance response on 2022/2/16. The reviews included 1) Product technical documents and general information, 2) on-site inspection
- US FDA conducted on-site inspection between 2022/6/7 to 6/16, at EirGenix's Zhubei facility, and collaboration partner's facility, and provided Form 483 for observations on 6/16，with no major or critical findings. EirGenix and collaboration partner responded within 15 days after FDA's on-site inspection, for the related improvement plans, also periodic reported back to FDA for improvement progress.
- During the review period, EirGenix had responded over 40 FDA's RFI (Request for Information) through Sandoz, include subjects on CMC/PK/Clinical) ，and 17 RFIs came through after FDA's on-site inspection.
- It is US FDA's standard review process, and Sandoz only received FDA's CRL (complete response letter) on 2022/12/13. Regardless of the on-site inspection outcome, on paper inquiry only finished in November, and received official results in December.

EG12014

Trastuzumab Biosimilar - EG12014 (HERWENDA® - Sandoz | EIRGASUN® - EirGenix)

| US FDA BLA (Biologic License Application) Follow-up

- 2023 Q1 EirGenix and its DP backend manufacture collaborating partner will focus on improving aseptic filling and lyophilization SOP and manufacturing equipment, till it meet the satisfactory resolution of the FDA observations and plans a BLA resubmission in due course.

- Once US FDA accepted RESUBMISSION, it is required to conclude within 6 months.

| EU EMA (European Medicines Agency) MAA (Marketing Authorization Applications)

- **Still ongoing. Part of the review depends on US FDA's review outcome. Expect to conclude in 2023 Q2/Q3.**

| Taiwan TFDA NDA (New Drug Application)

- **EirGenix submitted Taiwan TFDA for NDA on 2022/9/30**
- **TFDA conducted on-site inspection at EirGenix's Zhubei facility between 2022/1/19 to 1/20, and received inspection approval on 8/9**
- **TFDA conducted on-site inspection at EirGenix's DP backend manufacture collaborating partner facility between 2022/3/17 to 3/18, and received inspection approval on 12/23**
- **Licensing approval review schedule on track, expect to conclude in 1H 2023**

Duration for Global Biosimilar Drug To Receive US FDA Approval

Trastuzumab (Herceptin) Biosimilar as example

	Submission	CRL	Re-submission	Approval	Overall Duration
Mylan	2016/11/3	NA	major amendment: 2017/7/28	2017/12/01	13 months
Celltrion	2017/5/30	2018/3/30	2018/6/15	2018/12/14	19 months
Pfizer	2017/6/22	2018/4/20	2018/9/28	2019/3/11	21 months
AMGEN	2017/7/28	2018/5/25	2018/12/28	2019/6/13	23 months
SAMSUNG	2017/10/20	NA	major amendment: 2018/7/30	2019/1/8	15 months

End of the Presentation

Q & A

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