

# PharmaLedger Association Annual Report 2022

## Message from the Executive Director

2022 saw the creation of the PharmaLedger Association with the mandate to carry on the journey started by the PharmaLedger project. Despite many challenges, the PharmaLedger Association (PLA) finished the year in a unique position "to enable and foster a Digital Trust Ecosystem (DTE) in healthcare through a standardized and trusted open-source platform."

What makes PLA unique? As a nonprofit originating from a public-private partnership, with proven capability to collaborate and deliver results, PLA is the proof that a diverse set of stakeholders can share a common vision and engage to make a better future a reality. Core values that guided the project are now embedded in its bylaws. Inclusive membership and governance create transparency and trust.

There is certainly a long way to go, and the association will face many hurdles. Of primary importance is to deliver on the original strategy to launch our first product and to attract and retain new members. These challenges do not block the path forward, they <u>are</u> the path! I look forward to combining our forces in the year ahead to make a Digital Trust Ecosystem in healthcare a reality, and to make PLA a preferred way to solve problems that can't be solved alone. With passionate people and organizations as staff and members, there is no limit to what PLA can ultimately accomplish.

I would like to personally thank the original directors of the PLA, Maria Teresa Arredondo Waldmeyer and Marco Cuomo, for their strong support during the formative phase of the association and for their continued engagement to make healthcare better for patients.

Daniel Fritz
Executive Director
PharmaLedger Association

#### PharmaLedger Association Purpose

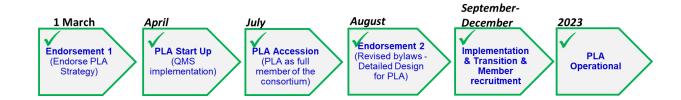
PharmaLedger's purpose is to create a "Digital Trust Ecosystem" (DTE) for healthcare by designing, developing, and implementing platform underpinned with blockchain which supports value creation through open-source decentralized applications (DApps). Patients, industry, Health Care Providers, regulatory authorities, governments, technical solution providers and others will be able to collaborate on solutions that bring mutual benefit.

The purpose of the association is defined in the bylaws and is a driving factor for its activities. PLA can generally pursue all initiatives that are in support of its purpose.



### Major Milestones and Achievements in 2022

2022 was a formative year for the PLA. Key milestones are outlined below.



**Endorsed PLA Strategy in March:** Following an extensive Due Diligence phase in the second half of 2021, the project consortium endorsed the PLA strategy on 1 March 2022 with the recommendation to create a not-for profit Swiss Association (Verein). The Association's primary focus was the implementation of a Quality Management System (QMS), required to ensure regulatory compliance.

**PLA Start Up in April**: The PharmaLedger Association was formally established on 31 March 2022 with four members - two individuals from Polytechnic University of Madrid (UPM) and two from Novartis, representing the industry project leadership and coordination. The association adopted a basic set of bylaws with the obligation to adopt an endorsed revised version of the bylaws in August.

**PLA Accession to the PharmaLedger Consortium in July**: The PharmaLedger Association was formally admitted to the PharmaLedger Consortium in a General Assembly vote on July 13. Through its accession, PLA was formally mandated to lead post-project sustainability, gained full access to the project results, and was entitled to leverage the industry cash commitment in support of formation activities.

**Endorsement #2 – Revision of bylaws in August**: The project's General Assembly endorsed a complete revision of the PLA bylaws on August 2. The bylaws redefined the purpose, values, organization, membership classes and fees.

**PLA Formation September to December**: PLA continued the implementation of the QMS system, developed a membership agreement and initiated recruiting of members. It further defined organizational policies and developed a transition plan for handover from the project to the association. PLA onboarded its first staff member (Executive Director) on 1 November and concluded the employment agreement for its second staff member (Quality, Trust, and Safety) to start on 1 January 2023.

**PharmaLedger Final Event 28-29 November**: The project celebrated over four years of preparation, planning and execution with a gala event in Madrid. The event highlighted the accomplishments of the project and served as a symbolic handover from project to operations by emphasizing the role of the PharmaLedger Association in the future.



## PLA Staffing and Resources

The PharmaLedger project scope included the creation and formation of PLA. The Governance and Operating Model work package delivered a detailed evaluation of the alternatives as well as due diligence of the alternatives in 2021. To support formation activities in 2022, the PharmaLedger project formed a cross-functional team consisting of representatives from Work Package 3 (Architecture and Reference Implementation), Work Package 4 (Governance and Operating Model), Work Package 6 (Culture and Adoption) and Work Package 7 (Project and Program Management). Remaining industry cash commitments provided the funding for the implementation of the Quality Management System, legal counsel, workplace infrastructure, software licenses, professional services and initial staffing.

It should be noted that including the governance and operating entity within the scope and timelines of the 36-month PharmaLedger project was a challenge. But the challenge was met through the combined efforts of the cross-functional team, the consortium as a whole, and support from the Innovative Health Initiative (IHI), who provided invaluable guidance and support.

As the project neared completion, it became clear that PLA had to be staffed and that the electronic Product Information (ePI) qualification would need to continue into 2023 as a functional project. Without the PharmaLedger project resources and with a nonprofit in its infancy, this presented another challenge. PLA was able to maintain the momentum for ePI created in the project through the commitment of business and technical resources from engaged Members. It was also able to retain project resources as initial staffing, both as actual employees or dedicated resources in the areas of quality, technology, ecosystem engagement and organizational leadership.

At the end of 2022, PLA had either onboarded or recruited enough members to ensure availability of resources to maintain PLA operations through 2023.

#### PLA branding and market entrance strategy

The PharmaLedger Association leverages the "PharmaLedger" brand name and a modified version of the project logo. This strategy was endorsed by the consortium and builds on the brand recognition established over the course of the project.

The strategy endorsed in the project and to be confirmed by the new Board of Directors is to launch ePI as a "Minimum Viable Product" in the first half of 2023 with a critical mass of members. Early adopters will pilot the solution in multiple markets and PLA will continuously improve the solution through quarterly releases.

PLA has launched a website and is continuing its social media presence, newsletters and engagement in industry conferences and events. When ePI is successfully launched, the plan



is to launch a more aggressive campaign of awareness and education through industry conferences and events, peer-to-peer interactions, and ecosystem engagement. We count on the engagement of members to help "spread the word" and serve as PLA ambassadors.

# **Financials**

PLA is a not-for-profit association. Membership fees are the primary source of revenue and will fund service provision and operations.

Funding of individual use cases will also support the Association. This funding can take the form of grants or donations from Sponsors.

PLA will rely on third-party services. PLA may also engage with like-minded third parties for integration of products or platforms.

Financial Reports

BILANZ	31.12.2022
	CHF
AKTIVEN	
Flüssige Mittel	116′794.38
Bankguthaben	116′794.38
Forderungen aus Lieferungen	
und Leistungen	260′000.00
Übrige kurzfristige Forderungen	4′337.20
Aktive Rechnungsabgrenzung	71′112.28
Umlaufvermögen	452′243.86
Mobilie Sachanlagen Büromaschinen, Informatik	5′670.00 <i>5′670.00</i>
A	F/C70.00
Anlagevermögen	5′670.00
	457′913.86

BILANZ	31.12.2022
PASSIVEN	CHF
Verbindlichkeiten aus Lieferungen und Leistungen	123.55
Übrige kurzfristige Verbindlichkeiten	8′158.60
Passive Rechnungsabgrenzung Vorauszahlungen Sonstige passive Rechnungsabgrenzungen	305′834.42 270′000.92 35′833.50
Fremdkapital kurzfristig	314′116.57
Fremdkapital	314′116.57
Periodengewinn von 3.5. bis 31.12.22	143′797.29
Vereinsvermögen per 31.12.	143′797.29
	457′913.86

ERFOLGSRECHNUNG	3.5. bis 31.12.22 CHF
Nettoerlös aus Lieferungen und Leistungen Zuschüsse, Förderbeiträge	384'093.00 <i>384'0</i> 93.00
Drittleistungen	-138′041.73
Bruttogewinn	246′051.27
Personalaufwand Lohnaufwand Sozialversicherungen Übriger Personalaufwand	-40'990.10 -33'333.30 -7'333.40 -323.40
Uebriger betrieblicher Aufwand Unterhalt, Reparaturen und Ersatz Versicherungen, Gebühren, Abgaben Verwaltungsaufwand Werbeaufwand	-44'739.97 -4'959.22 -51.50 -14'162.42 -25'566.83
EBITDA	160′321.20
Abschreibungen	-376.93
EBIT	159′944.27
Finanzaufwand	-146.98
Periodenerfolg vor Steuern	159′797.29
Direkte Steuern	-16′000.00
Periodengewinn von 3.5. bis 31.12.22	143′797.29

### **ANHANG ZUR JAHRESRECHNUNG**

Angaben über die in der Jahresrechnung angewandten Grundsätze Die vorliegende Jahresrechnung wurde gemäss den Vorschriften des Schweizer Gesetzes, insbesondere der Artikel über die kaufmännische Buchführung und Rechnungslegung des Obligationenrechts (Art. 957 bis 962), erstellt.

Die Rechnungslegung erfordert vom Vorstand Schätzungen und Beurteilungen, welche die Höhe der ausgewiesenen Vermögenswerte und Verbindlichkeiten sowie Eventualverbindlichkeiten im Zeitpunkt der Bilanzierung, aber auch Aufwendungen und Erträge der Berichtsperiode beeinflussen können. Der Vorstand entscheidet dabei jeweils im eigenen Ermessen über die Ausnutzung der bestehenden gesetzlichen Bewertungsund Bilanzierungsspielräume.

Sonstige Angaben	
	31.12.2022
	CHF
Anzahl Vollzeitstellen im Jahresdurchschnitt	weniger als 10