Napo Pharmaceuticals

The First Plant-Based Product Development Partnership

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The strategic dilemma

760,000

children under 5 die from diarrhea every year [24]

$300M+ / 20 years / 0 patients reached at scale

what Napo has invested vs what we've delivered

"How do we get our drug to the patients who need it without losing it again?"

Who we are: Napo

20 years

of plant-based drug development

70 communities

indigenous partners across 25 countries

2,300 plants

the largest ethnobotanical library in pharma

The drug: crofelemer

Croton lechleri · *the dragon's-blood tree*

Crofelemer

First-ever oral plant-based FDA-approved drug [1]

FDA approval: 31 December 2012

for HIV-associated diarrhea (40% of US HIV patients) [2]

Diagnosis: why both partnerships failed

Salix Pharmaceuticals 2008

- Had a competing drug (Xifaxan)
- Missed FDA filing deadlines
- Sued May 2011, terminated Nov 2011 [4]

Glenmark Pharmaceuticals 2005

- Rights in 140 emerging-market countries
- 0 regulatory applications in 6 years
- Arbitration ongoing

Same root cause: misaligned incentives [10]

A different model exists

Product Development Partnership (PDP)

DNDi

14 treatments / 6 diseases [6]

MMV

16 drugs / 811M patients treated [7]

Venture Philanthropy

CFF + Vertex

$150M invested [8]

Result

$3.3B royalty sale (2014) [9]

We propose: the first plant-based hybrid of these two models

SWOT analysis

Approved drug + scalable mission, but capital-light and litigation-shadowed

STRENGTHS

1. **FDA-approved** drug
2. **Largest** plant library in pharma
3. **20-year** supply chain

WEAKNESSES

1. **$7–10M** cash
2. **No** sales force
3. **Phase 3 effect:** 17.6% vs 8% [2]

OPPORTUNITIES

1. **PDP** funding ecosystem
2. **Orphan drug** pathways [16, 17]
3. **Priority Review** Voucher [18]

THREATS

1. **Salix / Glenmark** litigation
2. **Parallel trade** in EU
3. **Big Pharma** competitor

NET READ Defensible drug + unique platform; bridge cash and partner discipline are the win conditions.

Selection criteria + four pillars

Selection criteria

Cash preservation

Mission alignment

Strategic independence

Risk-adjusted EV

Four pillars

Pillar 1	Pillar 2	Pillar 3	Pillar 4
Salix royalties	**NP-500**	**Discovery platform**	**Venture philanthropy + IGO**

Pillar 1: Salix royalty stream

$4.5M	$500K	Royalties
upfront	equity	tiered on sales [3]

Alternatives evaluated

Lawsuit	*$9M cost, market window may close*	**REJECTED**
Glenmark appeal	*cannot afford it now*	**REJECTED**
Frozen partnership + passive royalties	*preserves cash, captures upside*	**SELECTED**

Pillar 2: NP-500 risk-sharing partnership

DEAL TERMS

$3M
upfront

$225M
milestones

7%
royalty [26]

WHY IT MATTERS

- Risk transfer
- Non-dilutive
- Credibility
- Operational

CONTRACT DESIGN

- Hard milestones
- Quarterly reports
- Carve-outs

30% higher FDA approval rate from pharma–biotech partnerships [14]

Pillar 3: Discovery platform as PDP hub

2,300
plants

›

Screen
& evaluate

›

1
FDA-approved
(crofelemer)

›

100s
potential more

Three tracks

Track A

PDP partnerships

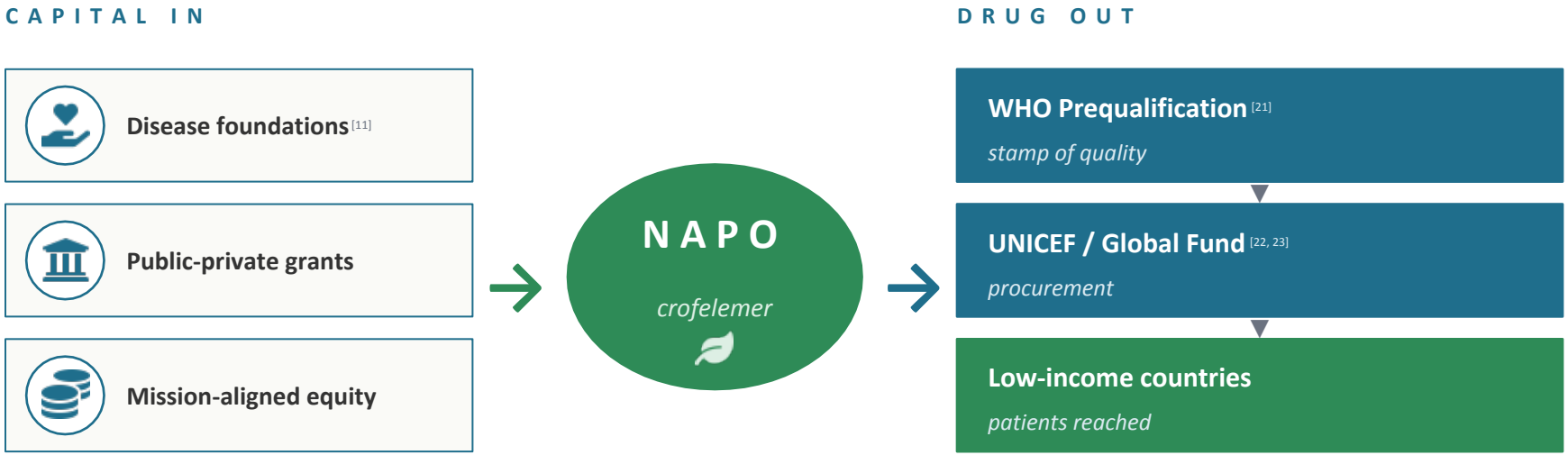
Track B

Academic licensing

Track C

Harvesting infrastructure as a service

Pillar 4: Venture philanthropy + IGO distribution



Bonus upside: **Priority Review Voucher (FDASIA Section 908)** [18] *HTA pricing: NICE / IQWiG [13, 15]*

Upside, protection, and risk

Three things investors should weigh: where it goes right, what protects us, and how we've planned for what could break.

UPSIDE 2

Track 1: Western markets

IBS — $4B opportunity [27]

Track 2: Developing world

UNICEF / MSF / Global Fund

PROTECTION 3

Patents to 2028

Botanical Drug Guidance [19]

20-year supply chain

RISKS → MITIGATION 5

1. NP-500 delay → **4-pillar resilience**
2. Salix never launches → **Royalty pillar = 0**
3. Parallel trade → **IGO routing**
4. Amazon supply chain → **4 countries**
5. Competitor entry → **Patents + moat**

Financials — base case

Three-year cumulative — income, operating burn, ending cash.

INCOME

$25–30M

cumulative — Salix milestone, NP-500, grants

→

BURN

$18M

operating burn — staff, R&D, supply chain

→

ENDING CASH

$16M

Year 3 — base case

BREAK-EVEN	BASE ROI	EXIT
Year 3	1.5–3×	$50–100M / 3–5×

Sensitivity — does the plan survive?

Three downside scenarios, severity-coded by impact on the plan.

STILL VIABLE

20% slower NP-500 partnership

$12M ending cash

MEANINGFUL HIT

Competitor enters earlier than expected

NP-500 deal value drops, but deal still happens

HEDGED BY DESIGN

Salix never launches commercially

Royalty pillar = 0

BOTTOM LINE *No single failure breaks the plan — that is the point of the four-pillar architecture.*

"Three things have to be true at once for Napo to work: the drug reaches the patients who need it, the indigenous communities we work with share in the success, and the company makes enough money to keep going. The four pillars are how we do all three."

Sanya & Aida · Napo Pharmaceuticals · January 2013

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