Hyloris PHARMACEUTICALS

Annual Results 2022

Webcast presentation

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Forward-Looking Statements

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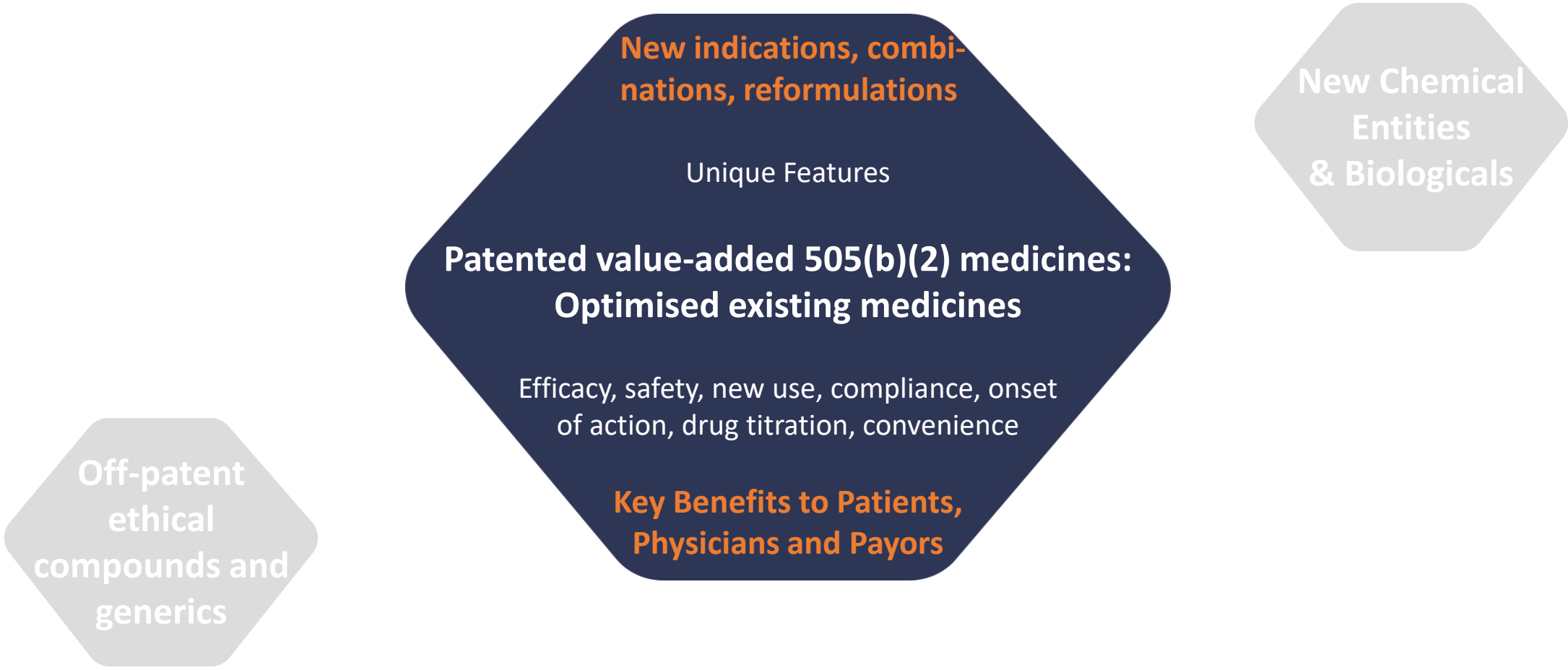
Agenda for Today's Call

- New product candidates
- Commercial milestones
- Pipeline expansion
- Financial position
- Expected milestones (12 months)
- Q&A

Patented Value-Added Medicines: Pharma's Sweet Spot



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Pipeline expansion: ~30 Assets before 2025

Addressable market

Market size	7% of population
Absolute numbers	~ 19 million patients in the US ~ 25,8 million patients in Europe
Seeks specialist treatment	13% of the above, following ~8 years of trial and error

HY-083

Nasal Administration

Indication: Idiopathic rhinitis (chronic rhinitis without a known cause)

Unmet medical need: providing first reliable treatment

Symptoms: Runny nose, stuffy nose, sneezing fits without a medical diagnosis (allergies, infection, inflammation, …)

- Impacting **quality of life** daily (sleep patterns, drowsiness, irritability, poor concentration)
- Molecule with known mechanism of action: block TRPV1 receptor in the nose
- Both **rapid** and **sustainable** relief

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Pipeline expansion: ~30 Assets before 2025

Addressable market

Market Size	5% of hospitalized patients*

HY-088 – January 2023

Oral liquid

Indication: **Phosphate deficiency (hypophosphatemia)**

Unmet medical need: No approved treatment exists today

- Phosphate deficiency is mostly asymptomatic
- Severe condition can be **life threatening** (respiratory or heart failure)

- Rich body of clinical data of widely used but unapproved treatment

- Always linked to **underlying condition**
- Condition affects 5%* of hospitalized patients
- **Direct treatment** for subpopulation during and/or after hospital stay

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* U.S. National Library of Medicine

Value-added portfolio, commercialized with partners

Product	Route of Adminstration	Indication	Formulation & Manufacturing	Clinical Development	Regulatory Filling	Target Market
Maxigesic® IV	Intravenous	Post-operative pain	***Licensed in >100 countries***			GLOBAL
Tranexamic Acid	Oral Mouth Rinse	(Dental) bleeding				GLOBAL
Miconazole - DB	Topical	Recurring VVC				GLOBAL
Alenura	Instillation	IC/BPS				GLOBAL
Plecoid Agent IV	Intravenous	AML and SCLC				GLOBAL
Atomoxetine	Oral Liquid	ADHD				USA
HY-029	Oral Liquid	Viral Infection				USA
HY-083	Nasal Spray	Idiopathic Rhinitis				GLOBAL
HY-088	Oral Liquid	Hypophosphatemia				GLOBAL

- ***Our high barrier generic products, TXA RTU, HY-016 and Fusidic Acid Cream have not been included in the above overview***

IV: intravenous ; RTU: ready to use; IM: intra-muscular

TXA: tranexamic acid
ADHD: attention deficit hyperactivity disorder
Miconazole-DB: miconazole-domiphen bromide
rVVC: recurring vulvovaginal candidiasis
AML: Acute Myeloid Leukemia
SCLC: Small cell Lung Cancer

Broad, innovative cardiovascular portfolio

Product	Route of Adminstration	Indication	Formulation & Manufacturing	Clinical Development	Regulatory Filling	Target Market
Sotalol IV	Intravenous	Atrial fibrillation	Up to 7 years			USA
Aspirin IV	Intravenous	Acute coronary syndrome				GLOBAL
Milrinone	Extended-release capsule	Advanced heart failure (LVAD)				GLOBAL
Dofetilide IV	Intravenous	Atrial fibrillation				USA
Metolazone IV	Intravenous	Congestive heart failure				USA
HY-074	Intravenous	Acute coronary syndrome				GLOBAL
HY-075	Oral Liquid	Coronary heart disease				USA

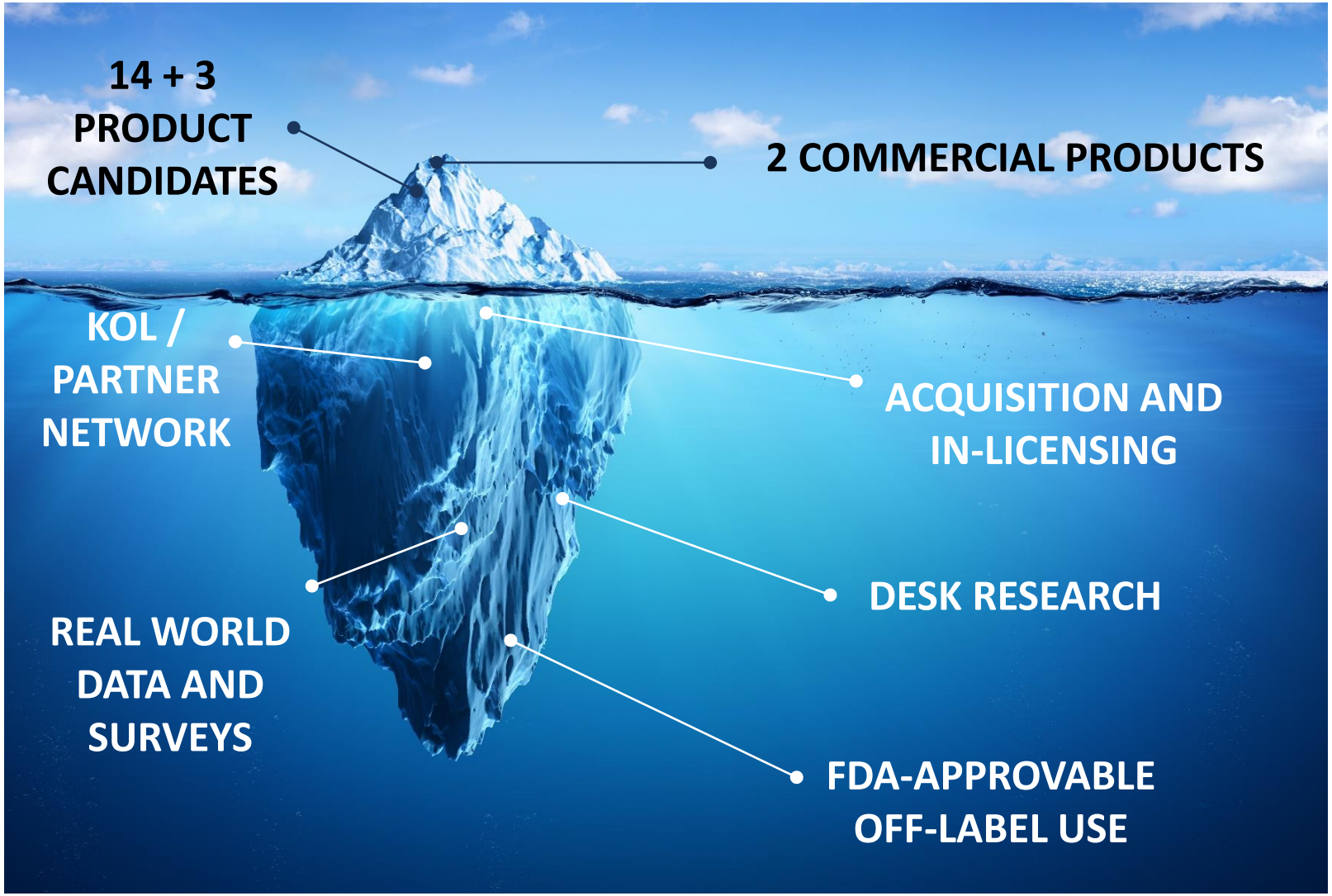
Intended to be commercialised by Hyloris in the U.S.

Intended to be commercialised with partner

LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood

- ***Our high barrier generic products, TXA RTU, HY-016 and Fusidic Acid Cream have not been included in the above overview***

Pipeline expansion: ~30 Assets before 2025



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Maxigesic IV: Significant Growth of Commercial Footprint

AFT pharmaceuticals + strong local distribution partners

Countries	H1 2023	H1 2020
Licensed	100+	80
Registered/ Approved	40	3
Launches	20+	-

Commercial roll-out:

- Out-licensing agreement in 9 additional European countries, registration completed in 5
- Additional licenses and approvals worldwide
- United States: NDA submission expected in H1, implying potential market approval in H2
- 4 U.S. patents granted to Hyloris, expiry between 2035 and 2039

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Commercial highlights

Sotalol IV

- Further commercial efforts to accelerate commercial roll-out in the United States

Tranexamic Acid RTU

- Out-licensing agreements
  - 1 European country
  - 1 Southeast Asian country
- Combined population of 60 million
- Ex-US potential exceeds internal expectations

HY-038

- €1 million out-licensing fee of non-core generic asset
- Increased focus on value-added repurposed candidates

Commercial progress
Focus on value-added product candidates
Strategic out-license agreements

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Financial Highlights 2022

(in € thousand)	2022	2021	% change
Revenue	**2,951**	**3,096**	**-4.7%**
Cost of sales	**-94**	**-107**	**/**
R&D	(10,151)	(5,056)	100.8%
G&A	(3,517)	(2,900)	21.3%
Other (income/expenses)	173	(5,573)	/
Operating Result	**-10,638**	**-10,541**	**0.9%**
Result of the period	**-10,770**	**-11,579**	**-7.0%**
Cash and cash equivalents	**43,457**	**50,012**	**-13.1%**

Key Factors

- Revenues:
  - Increased royalties in 2022 contribute more to current topline
  - Out-licensing fee of €1 million (HY-038)
  - 2021 revenue impacted by upfront milestone payment (€1.8 million) (Maxigesic IV)
- Operating expenses:
  - Higher R&D expenses, following portfolio expansion
  - Headcount grew from 21 (YE 2021) to 39 today

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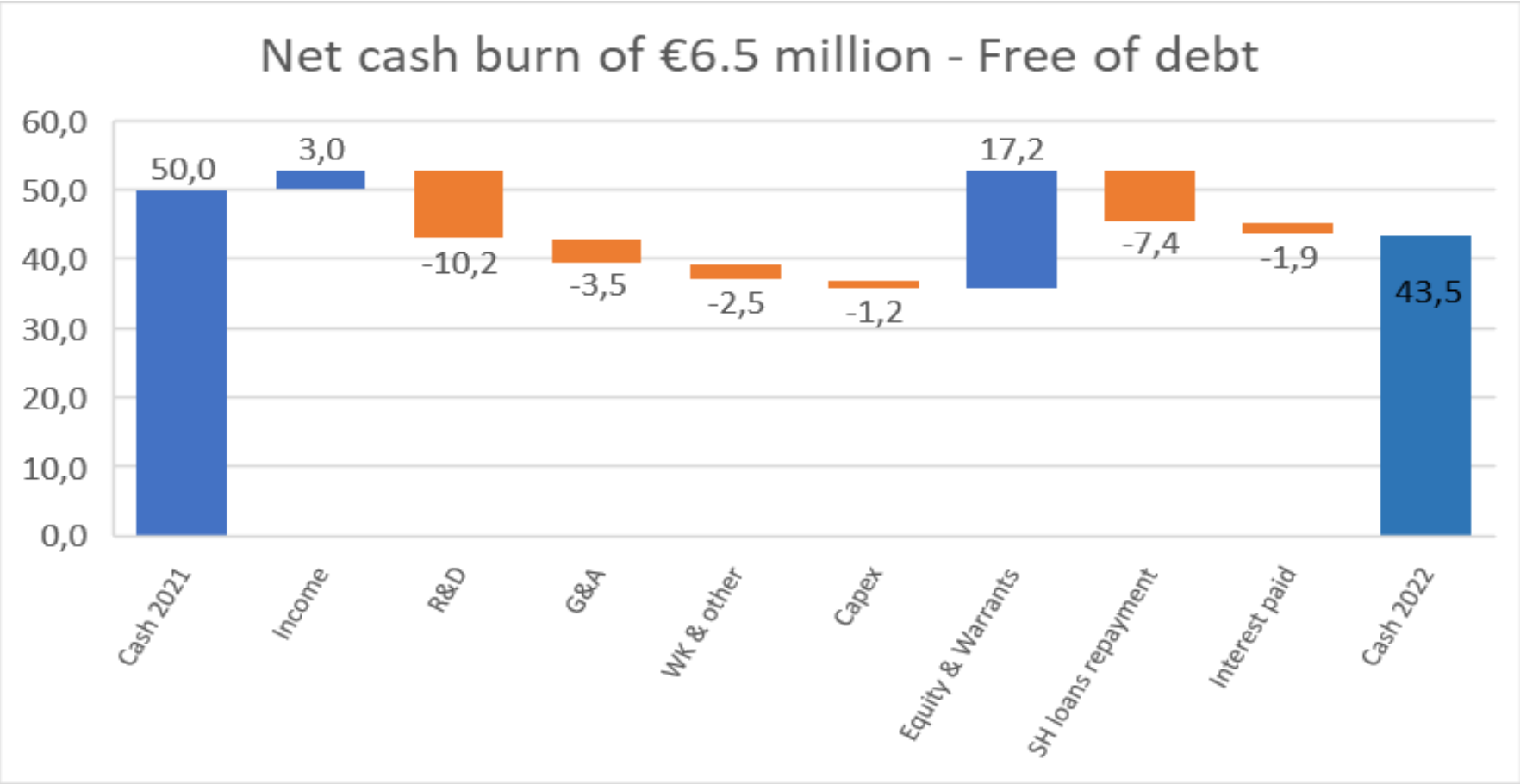
Financial position 31 December 2022



- Net cash burn of €6.5 million in 2022 - Cash position end of 2022 amounted to €43.5 million.
- Assuming additional out-licensing, commercial success of Maxigesic and Sotalol IV, additional non-dilutive funding and milestones payments, the Company is sufficiently capitalized to execute full development of its current pipeline assets(16+3)

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Anticipated Value Inflection Milestones in the next 12 months

Clinical

- Alenura™ starting multiple trials, among which four-arm phase 2 clinical trial
- Miconazole/DB: Phase 2 top line results in H1 2023
- Starting Phase 3 clinical trial on HY004 (Tranexamic Acid Oral Mouth Rinse)
- HY-029 and Dofetilide IV: start pivotal PK studies

Regulatory

- Maxigesic® IV in the U.S. Submission before summer 2023

➔ Potential NDA approval before end of 2023

- Global market authorizations for Maxigesic® IV

Commercial

Commercial partnership(s)

- Out-licensing deal(s)
- In-licensing deal(s)

Ambition to expand the product portfolio to ~30 assets before 2025

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NDA: new drug application


Q&A

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