Island Pharmaceuticals

ILA.AX

MST Access

A research platform of MST Financial

6 February 2024

SAD Trial Cohort 3

NEED TO KNOW

- 3rd cohort in SAD[1] clinical study dosed
- SAD study to confirm dosing for Phase 2a trial
- Cash at Dec 31, 2023 was A$1m

ILA has announced that the third cohort of Single Ascending Dose (SAD) study has been dosed. The data will be added to Cohorts 1&2 to establish the effective and safe dosing for ILA's clinical trial program. **The results of the SAD study are anticipated for early CY24.**

With confirmation of the dose, ILA plans to **commence its PEACH Phase 2a clinical trial** to provide first clinical data in dengue infected subjects.

Market dynamics are favourable. There is no approved Dengue Fever (DF) treatment and challenges for the two 'approved' preventative vaccines.

Further funding will be required with cash at Dec 2023 of A$1m.

Investment Thesis

Clear unmet need: There is no effective therapy and limited use of preventative vaccines. ILA is believed to likely offer both preventative and therapeutic roles.

Expanding potential market: The United Nations described 2023 as a 'horror year', with the ongoing spread of DF into southern EU and US.

ISLA-101 has the potential to be used in multiple indications: The mechanism of action of ISLA-101 supports potential application in Yellow Fever virus, West Nile virus, Japanese encephalitis and Zika virus.

Valuation

MST's 12-month forward valuation of A$26m, $0.19ps (unchanged), is based on the average market capitalisation of a cohort of ASX-listed biotechnology companies in Phase 1/2 trials, a similar stage of development. Upside risk presents with FDA confirmation for the commencement of the Phase 2a trial. MST also notes that data from the SAD study may allow for adaption of the planned clinical program, potentially bringing time savings and reduced costs.

Risks, Sensitivities

The valuation is subject to the usual drug development risks; regulatory approval, market entry, market size, market share, pricing, drug supply, competitor products, timing and potential licensing metrics – all may differ to MST assumptions, presenting upside/downside risk. MST notes realisation of the valuation over the short term will be difficult but expects positive trial results in FY24 to see a re-rating of the stock.

Equities Research Australia

Biotechnology & Plasma Products

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ISLAND PHARMACEUTICALS

Antiviral therapeutics

ASX listed Island Pharmaceuticals (ILA.AX) is a drug research company, focused on repurposing drugs to prevent and/or treat viral illnesses. Repurposed drugs potentially offer shorter, lower cost routes to market and a higher probability of approval. ILA's first target is dengue infection. Its lead drug candidate, ISLA-101 (fenretinide), offers application in a number of other viral related illnesses. ILA aims to build a strong pipeline of drug candidates through in-licensing agreements and acquisition.

www.islandpharmaceuticals.com

Valuation	**A$0.19 ps** *(unchanged)*
Current price	**A$0.09 ps**
Market cap	**A$7.3m**
Cash on hand	**A$1m**

Potential Upcoming Catalysts and Newsflow

H1CY24 – Read out of SAD study

CY24 – Confirmation and commencement of Phase 2a trial

Share Price (A$) Performance

Source: FactSet, MST Access

[1] Single Ascending Dose

Figure 1: Financial Summary

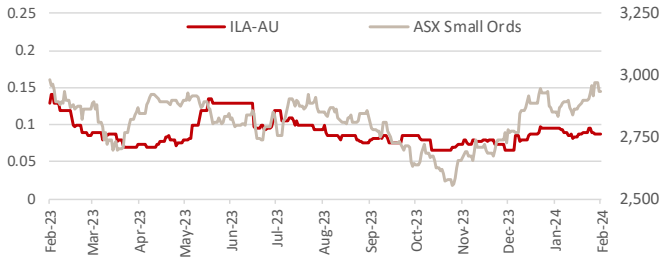
Island Pharmaceuticals Limited — ILA-AU

Year end 30 June

MARKET DATA

Share Price	**A$**	**0.08**
52 week low / high	A$	0.15-0.061
Valuation (12 month forward)	**A$**	**0.19**
Market capitalisation	**A$m**	**7.2**
Shares on issue	m	81.3
Options	m	14.4
Other equity	m	40.0
Potential Shares on issue (diluted	m	135.7

12 month performance



INVESTMENT FUNDAMENTALS		FY22	FY23	FY24E	FY25E	FY26E
EPS Reported (undiluted)	¢	(3.2)	(3.5)	(3.5)	(2.5)	(2.2)
EPS Underlying (undiluted)	**¢**	**(3.2)**	**(3.5)**	**(3.5)**	**(2.5)**	**(2.2)**
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**	**-**

KEY RATIOS (A$)		FY22	FY23	FY24E	FY25E	FY26E
Forecast year end shares	m	81	81	106	106	121
Market cap (Y/E / Spot)	**$m**	**6.5**	**6.5**	**8.5**	**8.5**	**9.7**
Net debt /(cash)	$m	(4.8)	(1.4)	(3.7)	(1.0)	(3.4)
Enterprise value	**$m**	**1.7**	**5.1**	**4.8**	**7.5**	**6.3**
EV/Sales	x	n/a	n/a	n/a	n/a	n/a
EV/EBITDA	**x**	**(0.7)**	**(1.8)**	**(1.5)**	**(2.9)**	**(2.4)**
EV/EBIT	x	(0.7)	(1.8)	(1.5)	(2.9)	(2.4)
Net debt / Enterpprise Value	x	(2.8)	(0.3)	(0.8)	(0.1)	(0.5)
Gearing (net debt / EBITDA)	**x**	**1.8**	**0.5**	**1.1**	**0.4**	**1.3**
Operating cash flow per share	$	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Price to operating cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow	**$m**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow per share	$	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Price to free cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow yield	**%**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Book value / share	$	0.05	0.01	0.03	0.01	0.03
Price to book (NAV)	**x**	**1.5**	**5.5**	**2.4**	**8.3**	**2.8**
NTA / share	$	0.05	0.01	0.03	0.01	0.03
Price to NTA	**x**	**1.5**	**5.5**	**2.4**	**8.3**	**2.8**
EBITDA margin	%	n/m	n/m	n/m	n/m	n/m
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	n/m	n/m	n/m

PROFIT AND LOSS (A$)		FY22	FY23	FY24E	FY25E	FY26E
Revenue & Other Income	$m	-	0.0	0.4	-	-
Expenses	$m	(2.6)	(2.8)	(3.7)	(2.6)	(2.7)
EBITDA	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.7)**
D&A	$m	-	-	-	-	-
EBIT	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.7)**
Interest	$m	-	(0.0)	-	-	0.1
Pre-tax Profit	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.6)**
Tax	$m	-	-	-	-	-
Underlying NPAT	**$m**	**(2.6)**	**(2.8)**	**(3.3)**	**(2.6)**	**(2.6)**

BALANCE SHEET (A$)		FY22	FY23	FY24E	FY25E	FY26E
Cash	$m	4.8	1.4	4.1	1.0	3.4
Receivables	$m	0.0	0.0	0.0	-	-
Inventory	$m	-	-	-	-	-
PPE	$m	-	-	-	-	-
Other	$m	0.1	0.0	0.0	0.0	0.0
Total Assets	**$m**	**4.9**	**1.5**	**4.1**	**1.1**	**3.5**
Creditors	$m	0.5	0.2	0.2	-	-
Borrowings	$m	-	-	0.4	-	-
Other	$m	0.0	0.1	0.1	0.1	0.1
Total Liabilities	**$m**	**0.6**	**0.3**	**0.6**	**0.1**	**0.1**
Shareholder's equity	**$m**	**4.3**	**1.2**	**3.5**	**1.0**	**3.4**

CASH FLOW (A$)		FY22	FY23	FY24E	FY25E	FY26E
Receipts from customers	$m	-	-	-	-	-
Payments to suppliers and employe	$m	(1.9)	(2.7)	(3.7)	(2.6)	(2.7)
R&D rebate	$m	-	-	0.4	-	-
Milestones	$m	-	-	-	-	-
Interest	$m	-	0.0	-	-	0.1
Tax	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Operating cash flow	**$m**	**(1.9)**	**(2.7)**	**(3.3)**	**(2.6)**	**(2.6)**
Capex	$m	-	-	-	-	-
Acquisitions	$m	-	-	-	-	-
Other	$m	-	-	-	-	-
Investing cash flow	**$m**	**-**	**-**	**-**	**-**	**-**
Borrowings	$m	-	(0.2)	0.4	(0.4)	-
Equity	$m	-	-	5.0	-	5.0
Dividend	$m	-	-	-	-	-
Financing cash flow	**$m**	**-**	**(0.2)**	**5.4**	**(0.4)**	**5.0**
Change in Cash / FX	$m	(1.9)	(2.9)	2.1	(3.1)	2.4
Year end cash	**$m**	**4.8**	**2.0**	**4.1**	**1.0**	**3.4**

Source: MST, Company Reports

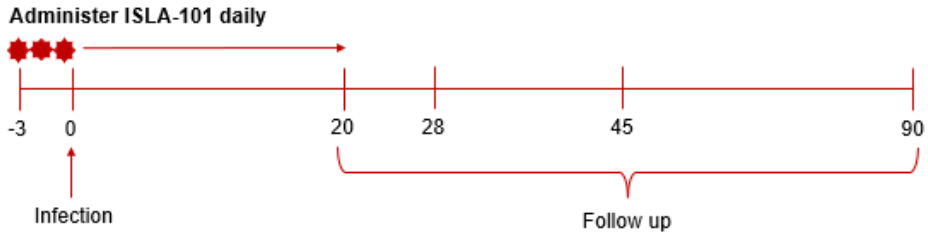
SAD study data to inform Phase 2a study

ILA has announced that the third and final cohort of its Single Ascending Dose (SAD) study has been dosed. The Data Safety Review Committee for its Single Ascending Dose (SAD) study has deemed that ISLA-101 was safe and tolerable for all three cohorts. The blood samples will be analysed by a laboratory to determine the blood concentration levels of ISLA-101.

The results for the study are planned for early CY24. The aim of the SAD study is to select a dose that is safe and predicted to be effective against the dengue virus in furtherance of the clinical trial program. ISLA-101 is an oral formulation. The studies to date have been undertaken with the candidates under fasted conditions. Following the selection of cohort with the highest safe dose, the dose will be repeated with the candidates under 'fed' conditions to determine if there is any effect from the absorption of food to the drug uptake.

ILA's PEACH Phase 2a clinical trial is planned to be a randomized, double blind, placebo-controlled study to investigate ISLA-101 in a prophylactic (disease preventing) role against dengue.

Figure 2: PEACH Phase 2a Clinical Trial Design



Inclusion

- Healthy Subjects
- Age 18 – 65
- Willing to use contraception for the duration of the study
- Informed consent

Primary endpoint

- Assess the prophylactic effect of ISLA-101 on fever, clinical symptoms, laboratory abnormalities and viremia after challenge with DENV-1-LVHC

Secondary endpoints

- Characterize the clinical, immunologic and virologic responses following ISLA 101 after challenge with DENV-1-LVHC
- Assess the safety of ISLA 101 in the challenge with DENV-1-LVHC

Source: ILA

Potential for ISLA-101 in current markets

ISLA101 offers potential roles as both a therapeutic and preventative therapy. From a competitive perspective, there is no approved therapy for Dengue Fever. Treatment is essentially confined to managing the presenting symptoms. Preventative therapies include two approved vaccines noting neither has had a straightforward path.

Preventative dengue market

- Sanofi (SYN) Pasteur's Dengvaxia® was first approved in 2015. Approval was granted in Europe and ~20 countries. The emergence of serious adverse effects in recipients who had not been exposed the dengue virus prior to vaccination has seen its use substantially limited. In 2019, the US Food and Drug Administration (FDA) approved the vaccine for children aged 9 to 16 years who have laboratory-confirmation of a previous dengue infection and live in areas where the disease is prevalent, such as Puerto Rico, the U.S. Virgin Islands and American Samoa.

- In 2023, Takeda Pharmaceuticals' (NYSE:TAK) QDENGA® (TAK-003) preventative Dengue Fever vaccine was approved by the EU's Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). The vaccine has also been approved in the United Kingdom, Brazil, Argentina, Indonesia, and Thailand. However, ongoing queries from the FDA has seen TAK voluntarily withdraw the U.S. Biologics License Application (BLA). TAK has stated that the future plan for TAK-003 in the U.S. will be further evaluated given the need for travellers and those living in dengue-endemic areas of the U.S.

Potential therapeutic market opportunity

As discussed, there are no approved treatments. The unmet need attracts interest in the sector. ISLA-101 joins a busy field of potential new entrants.

Figure 3: A busy field of potential Dengue Fever therapeutics

Dengue Fever therapeutics in clinical testing

Drug name	Pre-clinical data	Clinical data	Route of administration	Trial stage
JNJ-64281802	Antiviral activity in vitro was shown for its analog, JNJ-A07. Decrease in viremia, viral burden, and inflammatory cytokines, and improved survival in immunocompromised mouse model of DENV infection	Clinical trials for dengue prophylaxis in healthy individuals (NCT05201794) as well as for dengue therapy in patients with confirmed dengue fever (NCT04906980) are in progress	Oral	Phase 2 completed
Eltrombopag		Randomized open-label placebo-controlled trial (n = 101) showed improved platelet recovery, increased platelet count, and reduced bleeding manifestations in grade II DHF patients (SLCTR/2019/037)	Intravenous	Phase 2 completed
UV-4B	Antiviral activity in vitro and in vivo	Phase 1a clinical trial (NCT02061358) with healthy subjects indicated that a single dose up to 1000 mg of UV-4B was safe and well tolerated	Oral	Phase 1a completed
Zanamivir	Reduction in DENV2 NS1-induced endothelial hyperpermeability and vascular leakage in vitro	Clinical trial to test efficacy against vascular leakage (NCT04597437) is currently on-going	Oral	Phase 1
VIS513	Diminished circulating infectious DENV in NHPs , and reduced viral load with improved survival in immunocompromised mice models of DENV infection	Clinical trial in progress (CTRI/2021/07/035290)	Intravenous	Phase 2
Ketotifen	Reduced vascular leakage in mouse models of DENV infection	Clinical trial in progress (NCT02673840)	Oral	Phase 2
Montelukast	Reduced vascular leakage in mouse models of DENV infection [18]	One randomized open-label clinical trial (n = 200) reported reduced incidence and relative risk of DSS (narrow pulse pressure < 20 mmHg and hypotension for age) [95]. A randomized, double-blind, placebo controlled, superiority trial (NCT04673422) to test efficacy of montelukast is currently on-going	Oral	Phase 2/3
Rupatadine	Reduced vascular leakage in mouse model of DENV infection	Randomized placebo-controlled trial (n = 183) did not show reduction in leakage, but improved platelet counts and liver enzyme values (SLCTR/2014/023)	Oral	Phase 2
Metformin	Antiviral effect in DENV infected cells in vitro	A retrospective study (*n* = 223) showed decreased risk of severe dengue with metformin use in dengue patients with diabetes Clinical trial in progress (NCT04377451)	Oral	Phase 2
AV-1		Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Determine the Safety and Pharmacokinetics of AV-1 in Healthy Male and Female Adult Subjects	Intravenous	Phase 1
Dengushield		Study to evaluate the safety of a single dose of Dengushield (dengue monoclonal antibody) in healthy adults.	Intravenous	Phase 1

Source: Company reports

While clinical efficacy is yet to be established, ISLA potentially offers a number of advantages;

1. roles as both a therapeutic as well as a preventative therapy
2. as an oral dose, it allows for greater convenience and access for the therapy.

Funding

ILA reported cash of A$1m as at end of the CY23.

ILA's loan facility of A$118K at December 2023 is unsecured at a flat rate of 4.95%. It matures on June 7 2024. ILA announced in November CY23 that it had received ~$396K for the FY23 year under the Australian R&D Tax Incentive (RDTI). In December CY23, the company announced that it had negotiated a loan facility based on its forecasted FY24 RDTI. Under the loan facility, ILA is able to access up to 80% of its accrued RDTI. It received ~$386K in December 2023. The company expects to settle the loan in October 2024 upon receipt of its FY24 RDTI refund.

Investment Thesis

ILA's approach offers a number of investment advantages. They include;

- **Drug Repurposing Strategy**; in comparison to a first-in-human drug, as a re-purposed drug, fenretinide, offers safety data from 45+ clinical trials in cancer and other nonviral diseases. Safety accounts for some 30-45% of clinical trials failures. The existing data allows for reduced time, risk and cost – noting there are no clinical data to indicate its efficacy in viral illnesses.

- **Probability of Success**; review of drug approvals for drugs targeting infectious diseases demonstrates they carry a higher probability of approval. The average for all conditions of ~8% compares to ~13% for infectious diseases[2].

- **Challenge Model Clinical Trial Design**; ILA plans to conduct the study using a Dengue Human Infection Model (DHIM) or Challenge model. Challenge studies involve injecting healthy subjects with an attenuated dengue virus and then studying effects of the infection in a controlled setting. Challenge trials offer competitive benefits including: fewer subjects are required, faster execution as there is no requirement to wait for natural infection; stricter control over trial variables.

- **Potential PR classification and Priority Review Voucher (PRV);** ISLA-101 candidate is potentially eligible for being awarded a Tropical Disease PRV.

The key classification criteria include:

i) Be a drug or biological product for the prevention or treatment of a "tropical disease".

ii) The drug must meet the criteria for a priority review of application. A Priority Review designation may be awarded for drugs that would significantly improve the treatment, diagnosis, or prevention of serious conditions. It allows for expedited review where the FDA aims to take action on an application for approval within six months, compared to 10 months under standard review.

iii) The drug must contain no active ingredient that has been approved in any other therapy.

iv) Supply the clinical data that are essential to the approval of the application.

As the investor market has seen with NEU, a company that is awarded a PRV may choose to sell the voucher. At the end 2022 Bluebird Bio sold its for US$102m[3]. In 2023 Krystal Biotech (Nasdaq listed) announced it had sold its Rare Pediatric Disease Priority Review Voucher (PRV) for US$100m[4].

- **Expanding markets;** Dengue is already a major issue globally with up to 400m people infected each year, of which 100m show symptoms and ~40,000 die. The United Nations Office for the Coordination of Humanitarian Affairs (OCHA) described 2023 as a horror year for dengue5, with further expansion of the endemic areas. The current ~50% of the world's population at risk of dengue, is expected to continue to grow as global warming expands further into southern US,

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2 Clinical Development Success Rates Contributing Factors 2011-2020 Biotechnology Innovation Organisation et al

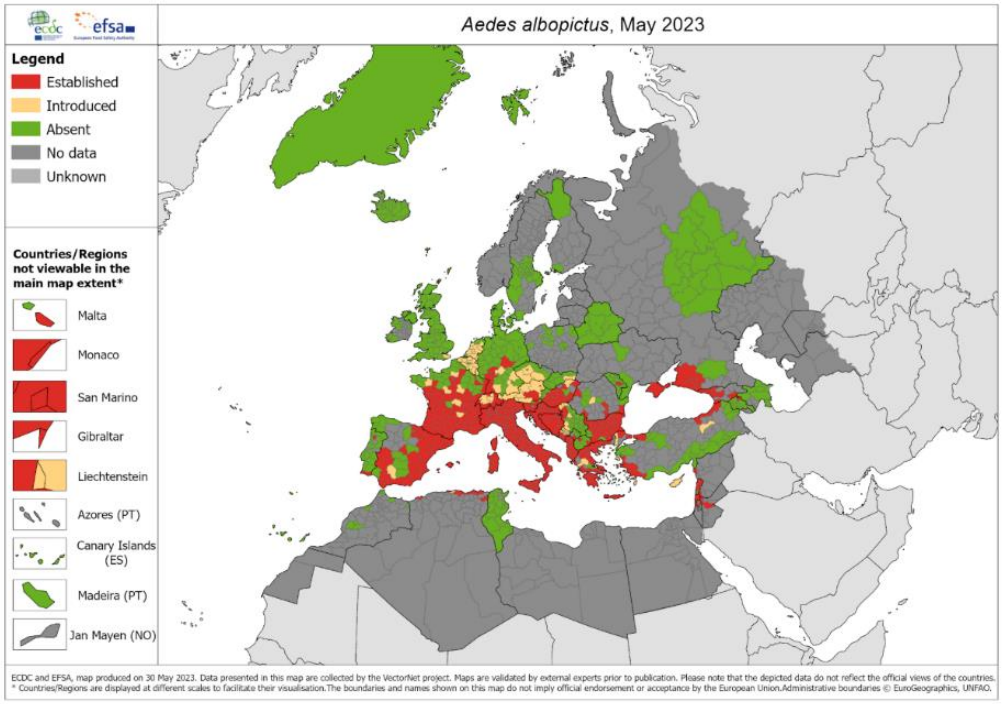
3 https://www.businesswire.com/news/home/20221130005434/en/bluebird-bio-Sells-Priority-Review-Voucher-for-102-Million

4 https://ir.krystalbio.com/news-releases/news-release-details/krystal-biotech-announces-sale-priority-review-voucher-100

5 https://reliefweb.int/report/world/dengue-fever-least-5-million-cases-and-5500-deaths-horror-year

southern Europe and new parts of Africa[6].

Figure 4: EU's northward Aedes mosquito spread increases risk of diseases like dengue



Source: The European Centre for Disease Prevention and Control (ECDC)

- **Additional Markets**; Preclinical studies support ISLA-101's mechanism of action in a number of related viruses including Yellow Fever, West Nile and Japanese encephalitis and Chikungunya. ILA's strategy for dengue can be leveraged in these diseases, offering the same advantages; faster timelines and cost efficiencies. The use of ISLA-101 in new indications has allowed for new patent filings that should offer market protection to 2034.
- **Highly Credentialled Partners**; ILA's approach is further supported by a retinue of noteworthy partners, US National Cancer Institute (NCI) and US Army and Camargo Pharmaceutical Services. The ILA Board offers a depth of scientific and commercial expertise.

Valuations, Risks, Sensitivities

MST's peer-based valuation of ASX listed companies undertaking Phase 1 trials derives an average market capitalisation of A$26m $0.19ps (unchanged). It compares to a current market capitalisation of A$7.2m. In MST's view, the discount reflects the uncertainty that has arisen from the FDA enquiries and delay to the planned start of the trial program. Completion of the SAD trial and confirmation of the commencement of its PEACH trial are likely to build investor confidence.

In MST's view, there is rationale for a premium for ILA. The key focus of Phase 1 and 2 trials is usually safety with early indications of efficacy often included in the Phase 2. As a repurposed drug, ISLA-101 offers strong safety data from over 45 previous clinical trials. The probability of approval rises from a Phase 1 of 13% to 23% from a Phase 2 trial[7]. Applying the premium to the comparable companies' average market capitalisation of A$26m, presents a valuation of A$46m[6].

MST also notes that in its view, the current market cap of A$7.2m does not recognise the potential value of PRV. Clinical data to emerge from the SAD study may see a re-rating of ILA. Upside/downside risks and sensitivities of drug development include clinical trial patient recruitment, timing and costs, regulatory approval and market entry, pricing, market penetration and sales, competitor drugs and potential royalties/licensing payments.

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[6] https://www.reuters.com/business/healthcare-pharmaceuticals/dengue-will-take-off-southern-europe-us-africa-this-decade-who-scientist-says-2023-10-06/

[7] *Clinical Development Success Rates and Contributing Factors - 2011-2020 chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020*

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