01/06/2022

Abliva

KL1333 Funded to Interim Readout

Sponsored Research

Price: SEK 0.36
Target Price: SEK 2.25

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The market has provided a fresh vote of confidence in Abliva, with SEK 200m of new funding now secured. This investment extends the runway to mid-2024, paving the way for a pivotal interim readout of their lead asset KL1333 by end-23/early-24. Trial preparations are now underway as the company intends to begin patient recruitment by the end of the year. Despite 59% share dilution, we value the shares at SEK 2.25, even with 20-25% risk adjustments, a WACC of 11% and fully accounting for future R&D cost to bring assets to approval.

Interim Readout by Early 2024 Will Show Way Forward

Abliva intend to rapidly recruit the first 40 of 120 patients in the trial so that they can appear in the interim analysis. This readout will determine the path forwards, with possibilities including continuation to final readout in early 2026, expansion of study, or even an early filing, in our view.

Earlier KL1333 Data is Highly Supportive of Positive Activity

In May 2021, Abliva reported strong early-stage data for KL1333 in 8 patients (6 treated with KL1333, 2 with placebo), showing dose-dependent improvements in two patient-reported fatigue endpoints and a functional endpoint, the 30-second Sit-to-Stand test.

FDA Validates Dual Primary Endpoints For KL1333's Pivotal Trial

KL1333's pivotal trial will have dual primary endpoints, meaning they can file on a positive outcome on either and this approach has been validated by the FDA. The statistical power of the dataset is reduced by just ~15%.

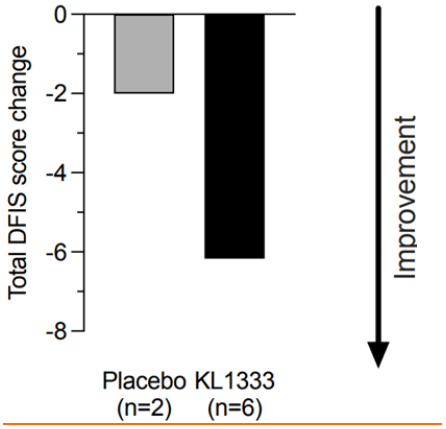
Investor Pool Broadened

This latest funding round has expanded Abliva's roster of investors to other high quality owners such as IP Group and the Norwegian fund OPF.

NV354 to Progress to Clinical Development

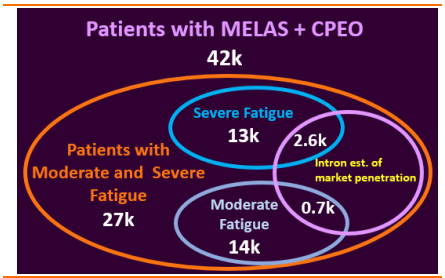
Abliva's second asset, NV354, also targeting a subset of mitochondrial diseases, received favourable feedback from the UK's MHRA and now that funding has been secured is able to move into clinical development.

Daily Fatigue Impact Score Change from Day 1 to Day 10



Source: Company reports

Target Population for KL1333 (Intron)



Source: Intron Health estimates

Summary Financials

	22E	23E	24E	25E
Sales (SEKm)	0.2	0.2	0.2	0.2
EPS (SEK)	-0.13	-0.07	-0.09	-0.18
Net cash (SEKm)	117.7	42.2	-45.9	-240.6
Market cap ($m)	15.1			

Source: Intron Health estimates

Contents

Q122 Results Were in Line

Last night, Abliva published their Q122 results, reporting a net loss of SEK 22m, in line with our expectations. More importantly, they also announced a SEK 200m raise (c. $20m) that will take place in June to finance the company through to mid-2024, with a key interim readout that is intended to be an important inflection point for Abliva, expected to occur by end-2023 to early 2024. This is a very positive and welcome development following on from KL1333's positive first-in-human readout last May.

Abliva Now Funded to KL1333 Readout

The main purpose of Abliva's SEK 200m raise is to finance KL1333's pivotal phase II/III study through to a key interim readout expected in late 2023 or early 2024. This study can now start to rapidly recruit the first 40 of 120 patients in H222, which is enough to provide the crucial safety and efficacy information at the interim readout to either continue with the study at 120 patients or expand it further if an increase in power is deemed to be necessary. The interim readout will also include a futility analysis. The company do not expect this interim readout to be fileable, but it is our belief, given that PMD is a serious disease with no current treatments, that if the interim readout shows very clear efficacy, they may be eligible to file for accelerated approval. Otherwise, the final readout is expected by early 2026.

NV354 to be Funded to Phase I

Around 5% of the SEK200m raised will be used to bring Abliva's second asset NV354 into clinical development. Clinical trial materials will be manufactured and regulatory submissions will be filed to enable a phase I start in the future.

SEK 200m Gives Runway to Mid-2024

Abliva intend to raise SEK 150m though a directed issue to a consortium of life science investors including IP Group and another SEK 50m by means of a fully underwritten rights issue. The subscription price of both issues is SEK0.35/share, a 10% discount to Abliva's share price at close on 31st May. The subscription period for the rights issue will run from 10th June to 27th June and for the purposes of our modelling we assume the shares are issued on 1st July. In total, 576m shares will be issued, with an additional 77m shares being created from the conversion of Hadean's convertible notes. The total dilution from all share issuances is around 59%. Following the SEK 200m raise, Abliva intends to run the business in a very lean manner, which should extend the runway to mid-2024, at which point another raise will become necessary but should be easily achievable with pivotal data from KL1333.

Table 1: Abliva's history of rights issues expected to continue

Shares (m)	2019A	2020A	2021A	2022	2023
Average share count for prior year	**78,500**	**171,575**	**250,321**	**370,168**	**729,653**
Issuance	93,075	78,746	80,025	326,646	0
Buybacks		0	0	0	0
Other		0	39,822*	32,839*	326,646*
Average share count for year	**171,575**	**250,321**	**370,168**	**729,653**	**1,056,299**
Actual number of shares on 31st Dec	185,953	296,340	403,007	1,056,299	1,056,299
Share issuance raise		**72,564**	**75,868**	**190,000**	**0**
Cash and cash equivalents	**58,319**	**61,643**	**22,339**	**117,736**	**42,236**

*Source: Company reports, Intron Health estimates * Adjustments for phasing of share issuances*

KL1333 to Initiate Pivotal Phase 2/3 Trial

The pivotal Phase 2/3 study for Abliva's lead asset KL1333 is expected to soon initiate following the SEK 200m raise and feedback from the FDA that the two selected alternate primary endpoints of "mitochondrial disease-specific fatigue" and "30-second Sit to Stand assessment" are suitable. These endpoints have been clinically validated and given the lack of treatment options, Abliva could potentially file if they hit either of them, effectively providing them with a double-shot at approval.

PMD-Specific Endpoints Validated

Following the completion of the validation study and FDA feedback, the dual endpoints of "mitochondrial disease-specific fatigue" and "30-second Sit to Stand assessment" have been selected as the primary endpoints.

- **Fatigue** is a hallmark of mitochondrial disease and will be assessed using a patient-reported fatigue outcome measure (based on NeuroQol and PROMIS fatigue ePROs) that the company validated for use in PMD patients. This measure considers factors including cognition, behaviour, communication, sleep and life participation.
- The functional **30-second Sit to Stand** endpoint consists of the scoring of subjects according to how many repetitions of sitting to standing they can achieve, with a higher score implying better muscle strength and endurance.

Study Design Gives Two Shots on Goal

Abliva have discussed their design for having two primary endpoints with the FDA and met with an encouraging response. They believe that if either endpoint is statistically positive, the trial is likely to be deemed a success. We understand that having dual endpoints is only expected to reduce the statistical power of the dataset by 15%, which seems like a sensible trade off to us. Additionally, due to the limited in-clinic participation required to conduct this trial (participants will attend in-clinic

settings a maximum of 4 times), this trial has a low risk of being adversely impacted by COVID and is therefore likely to remain on track.

Table 2: KL1333 Registrational Study Design

Trial	
Design	Randomised, double-blind, parallel- group, placebo-controlled (2 placebo: 3 active)
Patients	N=120-180 (Determined at interim futility analysis) Adult primary mitochondrial disease patients with: - Multisystemic mitochondrial DNA-related disease. - Chronic fatigue - Mitochondrial myopathy/ exercise intolerance
Regimen	Oral 2x daily dosing for 12 months
Endpoints	
Primary	Fatigue 30 Second Sit to Stand
Secondary	Clinician and Patient Global Impression of Disease Severity, NMDAS, patient specific activity assessments

Source: Company reports

KL1333 is a First in Class Treatment for PMD

KL1333 is an orally administered small organic molecule derived from β-lapachone, a quinone-containing compound obtained from the Lapacho tree. It is in development for the treatment of adults with primary mitochondrial disease, the majority of which will be within the spectrum of MELAS-MEDD and CPEO-KSS (together which account for approx. 40% of PMD). These diseases cause a wide range of severe symptoms, most particularly fatigue and there are around 40,000 patients in the US and Europe. The drug holds Orphan Drug Designation in both regions. Abliva in-licensed KL1333 from Yungjin Pharm and have exclusive global rights for the drug, excluding Korea and Japan.

KL1333 treats mitochondrial disease by increasing the concentration of NAD+ to normal levels. This increased NAD+/NADH ratio has a two-pronged effect which helps to treat the underlying condition by increasing ATP production and increasing mitochondrial biogenesis. Based on our assumptions, we believe the drug could generate up to $200m/year ($800m/year when fully de-risked) and we value it at SEK2.33/share based on a 2025 launch.

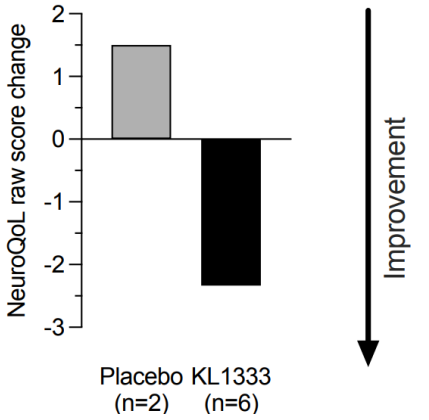
May-21 Data Was Highly Positive

In May 2021, Abliva reported positive human efficacy signals in their phase 1a/b trial for KL1333 in primary mitochondrial disease (PMD). This is the first human efficacy data that Abliva have reported for their lead asset and as such is an encouraging and important development.

The positive data was generated by a cohort of eight PMD patients within the study, six of whom were dosed with KL1333 and two with placebo. This cohort was not powered to show superiority, but the patients that received KL1333 had numerically superior improvements in two patient-reported fatigue endpoints and the 30-second Sit-to-Stand endpoint. For the latter measure, there was almost a 2 repetition difference from

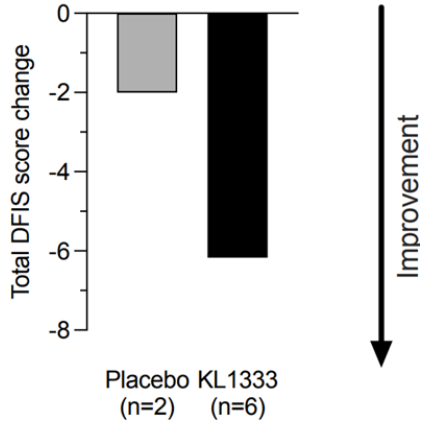
baseline - an improvement of ≥2 repetitions has been defined as the minimum clinically significant difference.

Chart 1: Neuro-QoL SF Fatigue Change from baseline to Day 10



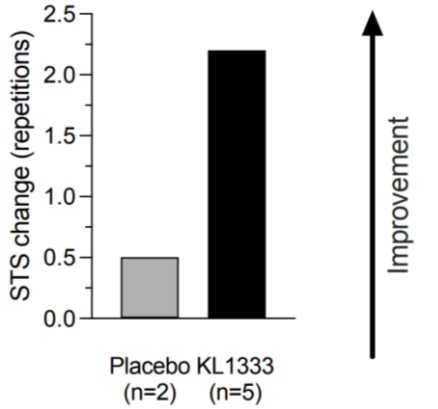
Source: Company reports

Chart 2: Daily Fatigue Impact Score Change from Day 1 to Day 10



Source: Company reports

Chart 3: 30s Sit to Stand Change from baseline to Day 10

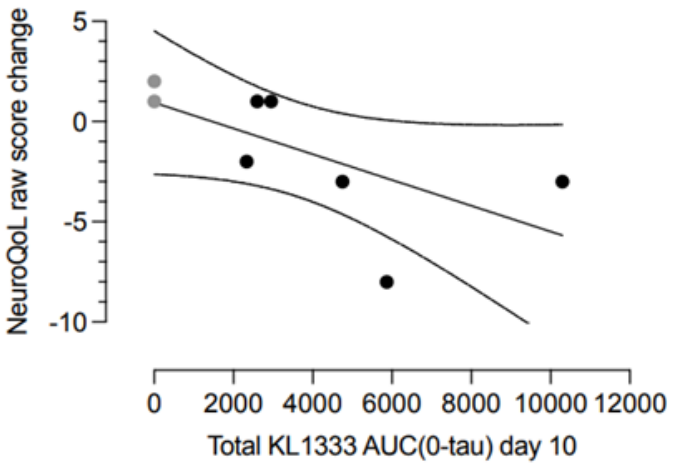


Source: Company reports

Improvements were Dose-Dependant

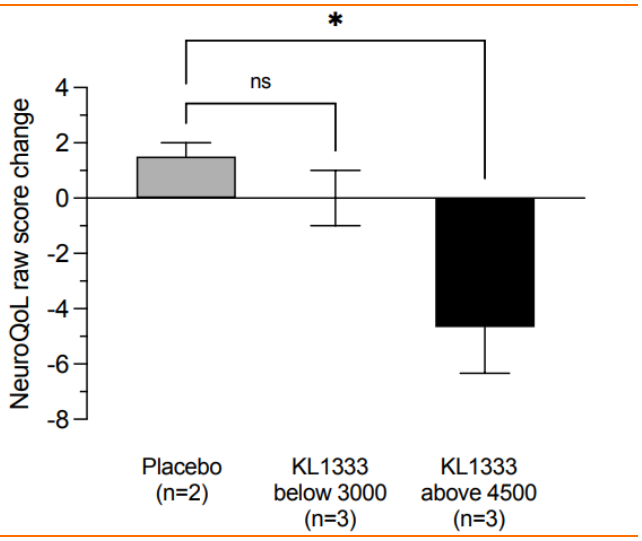
Importantly, a dose-dependent effect was found, implying that KL1333 was the likely driver of those differences. Only 10 days of dosing was carried out, so this data provides evidence that KL1333 also acts rapidly. Moreover, patients were only dosed up to 50mg/day of KL1333, which was deliberately low and in the next study this dose will increase to 100mg/day, so even stronger data is a possibility. No serious adverse safety signals were found in the trial (in both healthy volunteers or the eight person PMD cohort) and further supportive pharmacokinetic data was generated.

Chart 4: Neuro-QoL SF Fatigue



Source: Company reports

Chart 5: Neuro-QoL SF Fatigue



Source: Company reports

Good Safety Profile

KL1333 has a strong safety profile with over 100 healthy volunteers and patients dosed throughout development with no serious adverse events or safety signals. The asset is generally well tolerated with the main dose-limiting factor being gastrointestinal side effects, which was improved by administering smaller amounts of KL1333 two-three times a day rather than once.

In a completed pharmacology study assessing the interaction of KL1333 with seven CYP enzymes responsible for metabolising drugs, the asset was found to only mildly inhibit CYP1A2, one of the less common enzymes. As CYP enzymes are often essential for the metabolism of some medicines, this lack of significant inhibition is an important feature of KL1333 that should enable safe co-administration of other drugs.

We see ~6x Upside to Current Price

We value Abliva using a Sum-of-the-Parts methodology. We only value the cash flows over 2021-37 and do not include a terminal value in our calculations. We also use very high-risk adjustments (20-25%) and ignore some potential sources of value including off-label sales, regional sales outside of US/EU/UK and all of the R&D programmes outside of KL1333 and NV354. Our SOTP implies a target price of SEK2.25/share and assumptions include:

- WACC of 11%
- Tax of 21.4% (Swedish corporate tax rate after tax losses used up)
- R&D and G&A expenses to 2027 are NPV'd and deducted; this is sufficient to bring the two major drugs to approval and implies a future raise

Table 3: Intron Health valuation of Abliva

	Value (SEKm)	Value / share (SEK)
KL1333 (risk-adjusted)	2,457	2.33
NV354 (risk-adjusted)	424	0.40
Other revenues to 2025	1	0.00
Corporate & R&D costs to 2027	-527	-0.50
Net (debt) cash in 2022	118	0.11
Total (risk-adjusted) value	**2,472**	**2.34**
Target price		**2.25**
Share price	0.38	
Upside multiple	**5.9x**	

Source: Intron Health estimates

Financial Statements

Group P&L

Table 4: Abliva AB P&L

SEK (000s)	2021A	2022	2023	2024	2025	2026	2027	CAGR 22-27
Revenues	**151**	**151**	**151**	**151**	**151**	**140,243**	**471,179**	**399.9%**
growth	-30%	0%	0%	0%	0%	92776%	236%	
Cost of goods	0	0	0	-15	-15	-14,024	-47,118	
growth						N/A	236.0%	
as % of sales	0.0%	0.0%	0.0%	-10.0%	-10.0%	-10.0%	-10.0%	
Royalties paid out	0	0	0	0	0	-1,234	-4,556	
Gross profit	**151**	**151**	**151**	**136**	**136**	**124,985**	**419,505**	**388.4%**
Gross margin	**100.0%**	**100.0%**	**100.0%**	**90.0%**	**90.0%**	**89.1%**	**89.0%**	
External expenses	-103,695	-82,956	-66,365	-76,320	-152,639	-206,063	-247,275	24.4%
growth	125.1%	-20.0%	-20.0%	15.0%	100.0%	35.0%	20.0%	
as % of sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
Personnel cost	-16,844	-11,791	-9,433	-12,262	-30,656	-53,648	-75,107	44.8%
growth	26.6%	-30.0%	-20.0%	30.0%	150.0%	75.0%	40.0%	
as % of sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
D&A	-2,764	-2,529	-2,395	-2,268	-2,145	-2,987	-3,955	
as % of sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	
OOI/OOE	-330	0	0	0	0	0	0	#DIV/0!
as % of sales	-219%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	
EBIT	**-123,482**	**-97,124**	**-78,042**	**-90,714**	**-185,304**	**-137,713**	**93,167**	**-199.2%**
EBIT margin	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**-98.2%**	**19.8%**	
growth	105.6%	-21.3%	-19.6%	16.2%	104.3%	-25.7%	-167.7%	
Interest expense	-12	-12	-12	-12	-12	-12	-12	
Interest received	0	0	0	0	0	0	0	
Associates/JVs	0	0	0	0	0	0	0	
Pre-tax profit	**-123,494**	**-97,136**	**-78,054**	**-90,726**	**-185,316**	**-137,725**	**93,155**	
Tax	-4	0	0	0	0	0	-18,631	
Effective tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	-20.0%	
Net profit	**-123,498**	**-97,136**	**-78,054**	**-90,726**	**-185,316**	**-137,725**	**74,524**	
Minorities	6	0	0	0	0	0	0	
Net income	**-123,492**	**-97,136**	**-78,054**	**-90,726**	**-185,316**	**-137,725**	**74,524**	**-194.8%**
Number of shares (basic, 000s)	370,168	729,653	1,056,299	1,056,299	1,056,299	1,056,299	1,056,299	
EPS	**-0.33**	**-0.13**	**-0.07**	**-0.09**	**-0.18**	**-0.13**	**0.07**	**-188.1%**
growth	**39.2%**	**-60.1%**	**-44.5%**	**16.2%**	**104.3%**	**-25.7%**	**-154.1%**	

Source: Intron Health estimates

Group Balance Sheet

Table 5: Abliva AB balance sheet

SEK (000s)	2021A	2022	2023	2024	2025	2026	2027
ASSETS							
Intangible assets	21,503	19,843	18,249	16,719	27,250	39,360	50,986
PP&E	60	57	54	51	49	46	44
Associates	13,101	13,101	13,101	13,101	13,101	13,101	13,101
Other non-current assets	0	0	0	0	0	0	0
Non-current assets	**34,664**	**33,001**	**31,404**	**29,872**	**40,400**	**52,508**	**64,131**
Inventories	0	0	0	45	30	28,049	94,236
Trade/other receivables	912	1,003	1,104	1,214	1,335	1,469	1,616
Other current assets	1,003	1,003	1,003	1,003	1,003	1,003	1,003
Cash & cash equivalents	22,339	117,736	42,236	-45,949*	-240,620*	-417,196*	-419,081*
Non-current assets	**24,254**	**119,742**	**44,343**	**-43,687***	**-238,251***	**-386,676***	**-322,226***
Total assets	**58,918**	**152,743**	**75,747**	**-13,815***	**-197,851***	**-334,168***	**-258,095***
LIABILITIES							
Borrowings	0	0	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0	0	0
Non-current liabilities	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Borrowings	0	0	0	0	0	0	0
Trade payables	9,616	10,578	11,635	12,799	14,079	15,487	17,035
Provisions	0	0	0	0	0	0	0
Other current liabilities	7,774	7,774	7,774	7,774	7,774	7,774	7,774
Current liabilities	**17,390**	**18,352**	**19,409**	**20,573**	**21,853**	**23,261**	**24,809**
Total liabilities	**17,390**	**18,352**	**19,409**	**20,573**	**21,853**	**23,261**	**24,809**
EQUITY							
Share capital	20,150	20,150	20,150	20,150	20,150	20,150	20,150
Additional paid in capital	730,560	920,560	920,560	920,560	920,560	920,560	920,560
Translational reserves	688	688	688	688	688	688	688
Retained earnings (losses)	-709,879	-807,015	-885,069	-975,795	-1,161,111	-1,298,836	-1,224,312
Minority interests	9	9	9	9	9	9	9
Total equity	**41,528**	**134,392**	**56,338**	**-34,388**	**-219,704**	**-357,429**	**-282,905**
Total liabilities and equity	**58,918**	**152,743**	**75,747**	**-13,815**	**-197,851**	**-334,168**	**-258,095**

Source: Intron Health estimates

** Abliva will need to conduct a raise in 2024, but we do not currently forecast this due to the uncertainty of timing and amounts (but our valuation factors in these costs*

Group Cash Flow

Table 6: Abliva AB Cash Flow

SEK (000s)	2021A	2022	2023	2024	2025	2026	2027
Operating income	-123,482	-97,124	-78,042	-90,714	-185,304	-137,713	93,167
D&A	2,660	2,529	2,395	2,268	2,145	2,987	3,955
Other non-cash adjustments	512	0	0	0	0	0	0
Change in inventories	0	0	0	-45	15	-28,018	-66,187
Change in trade receivables	0	-91	-100	-110	-121	-134	-147
Change in trade payables	0	962	1,058	1,164	1,280	1,408	1,549
Other working capital movements	6,251	0	0	0	0	0	0
Interest received	0	0	0	0	0	0	0
Interest paid	-12	-12	-12	-12	-12	-12	-12
Tax paid	0	0	0	0	0	0	-18,631
Cash flow from operations	**-114,075**	**-93,737**	**-74,701**	**-87,450**	**-181,998**	**-161,482**	**13,694**
Purchase of PP&E	0	-5	-5	-5	-5	-4	-4
Disposals of PP&E	0	0	0	0	0	0	0
Purchase of intangibles	-1,024	-860	-794	-730	-669	-1,090	-1,574
Milestones paid out	0	0	0	0	-12,000	-14,000	-14,000
Cash flow from investment	**-1,089**	**-866**	**-799**	**-735**	**-12,673**	**-15,094**	**-15,579**
Proceeds from share issuance	75,868	190,000	0	0	0	0	0
Other	-76	0	0	0	0	0	0
Cash flow from financing	**75,792**	**190,000**	**0**	**0**	**0**	**0**	**0**
Beginning cash & cash equivalents	**61,643**	**22,339**	**117,736**	**42,236**	**-45,949***	**-240,620***	**-417,196***
Change in cash	-39,372	95,397	-75,500	-88,185	-194,671	-176,576	-1,885
FX impact	68	0	0	0	0	0	0
Ending cash & cash equivalents	**22,339**	**117,736**	**42,236**	**-45,949***	**-240,620***	**-417,196***	**-419,081***

Source: Intron Health estimates

** Abliva will need to conduct a raise in 2024, but we do not currently forecast this due to the uncertainty of timing and amounts (but our valuation factors in these costs*

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