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RESEARCH REPORT

LODGE PARTNERS

Factor Therapeutics

BUY

Just Quality Biotech with Significant Near-Term Catayst

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Company Data

Recommendation:	BUY
ASX code:	FTT
Share price at time of report	$0.06
Shares on Issue:	834.3m
Shares - fully diluted	1.0b
Market capitalisation – fully diluted	$62.3m
Cash (end March '18 + inflows since)	$10.0m
12-month price range	$0.036 - $0.070
Average Monthly Volume (Shares)	11.6m

Key Valuation Metrics

	Phase IIb Trial Success Rate (%)
Historical	30-40[1]
VF00102 share price implied	11.6
VF00102 analyst estimate	65

1 Based on various studies easily obtained on the internet

Factor Therapeutics (VF001)	NPV[a] (cents/share)
Current share price	6.0
Analyst estimate: **Before** phase IIb result	33.5
Analyst estimate: **+ve** phase IIb result	52.0

a Net present value based on fully diluted number of shares

Board & Management

Dr Cherrell Hirst	Chairwoman
Dr Rosalind Wilson	Chief Executive Officer
Mr Timothy Hughes	Non-exec. Director
Dr Christian Behrenbruch	Non-exec. Director
Mr John Michailidis	Non-exec. Director
Dr Robert Ryan	Non-exec. Director
Mr Nigel Johnson	Chief Operating Officer

Major Shareholders

Allan Gray Australia Pty Ltd	14.7%
FIL Investment Management (Hong Kong)	8.6%

Catalyst

Factor Therapeutics (ASX: FTT), in an update to the market today, stated that recruitment for its phase IIb trial (VF00102) of VF001 for the treatment of venous leg ulcers (VLUs) had completed recruitment. This makes it likely that the company will announce the results of the trial in Q4 CY18.

Given the significance of these results to the company and their relative near-term proximity, we believe that is a good time for investors to take a closer look at the company.

The Company

Factor is focused on wound care and, principally, on the idea that the linkage of a biological scaffold (something for cells to attach onto) and a factor which stimulates cell growth can be used to improve wound healing.

With a determination that VF001 was a device in Europe and a drug in the United States, Factor, then Tissue Therapies Limited (previously, ASX: TIS), focussed on Europe, initially, given the comparative ease of gaining approval for a device relative to a drug. For a while, the company found itself in regulatory limbo, as earlier advice that the product was a device was retracted. Ultimately, it was determined that the product could be classified as a device, but that the company did not have a large enough safety database to satisfy regulators.

At this point, a limited board re-shuffle was undertaken, new management was brought in, a new business plan developed, and, importantly, the company's intellectual property refreshed. The new business plan called for a clinical trial of sufficient size that it would satisfy the requirement for more safety data from European regulators, while also setting the product up for pivotal trials in the US as a drug, with a licensable data package around it.

The company does have other products and indications that it is pursuing, but the company really is about VF001 and its phase IIb clinical trial currently underway. **Therefore, it is on VF001 that we will concentrate and use as a proxy for valuing Factor.**

VF001

VF001 consists essentially of the protein, vitronectin (the scaffold) linked to the cellular growth factor, IGF-1, whose function is self-explanatory.

With VLUs, a case of chronic inflammation exists, leaving the wound bed denuded and a hostile environment for new skin growth, without the appropriate structures for skin cells to anchor themselves on to and begin to spread across the surface of the ulcer. **The hypothesis is that by applying VF001 to the wound bed, the vitronectin portion of the compound will create a framework for new cells to attach to, while the IGF-1 portion will stimulate epidermal (skin) cells to divide and migrate into the wound bed and, ultimately, allow the wound to heal.**

The product is designed to be used with the current standard of care, compression bandaging, by applying the liquid to the wound bed before the dressing and bandage are applied.

Venous Leg Ulcers

The Australian and New Zealand Clinical Practice Guideline for Prevention and Management of Venous Leg Ulcers (2011) contains some very useful information on VLUs and the following has largely been taken from that document and references therein.

Data on the prevalence of VLUs is generally poor and that appears to be due to the various methodologies used in collecting the data. What is clear is that VLUs are almost exclusively found in persons aged over 60 (99%), with a prevalence of about 3-4% in persons aged over 65. Importantly, they recur often. Recurrence rates have been estimated at between 22% to 70%, depending on the setting.

Compression bandaging (>30mmHg) for 12 weeks is considered the first line therapy. Patients with ulcers that have not decreased in size by 25% by four weeks or completely by 12 weeks should be considered for specialist referral. Once referred to a specialist, treatment can take various forms, including surgery, depending on the patient's individual characteristics. Factor believes that 94% of VLU patients are treated in the community setting (local physicians, community nurses, nursing homes, etc), as opposed to 6% in speciality care. Our research leads us to agree with these numbers.

Overall, it is clear that the market for VLUs is substantial in size and, to truly target that market, any proposed product should be suitable for use in the community setting. We are not aware of any other products currently being developed for use in the community setting for VLUs.

The Phase IIb VF001 Venous Leg Ulcer Trial (VF00102)

VLUs have not been a happy hunting ground for researchers or drug development companies, with compression bandaging having been the standard of care for decades now, with little change. That begs the question why Factor and VF001 should be any more likely to be useful than the other approaches that have been tried.

The answer, we believe comes down to the **well understood mechanism of action** of each of the components of VF001 and, extremely importantly, **clinical trial design**.

As per US Food and Drug Agency FDA) guidelines, healing rate at 12 weeks is the key endpoint for VLU studies.

Among the spectrum of VLU patients, there will be a certain number that will heal completely without any intervention within 12 weeks and there will be a certain number that simply do not heal during the 12 weeks regardless of any reasonable intervention, due to the underlying pathology of the ulcer. **These types of patients are, essentially, statistical dead weight and act to decrease the number of patients in which a difference between an intervention (e.g. VF001) and compression bandaging can be shown, making it harder to demonstrate a significant benefit (difference) with the intervention.**

This can be combatted by increasing the size of the trial, but then you can run into the issue of whether a clinically meaningful benefit has been shown. You may be able to show a statistical difference, but if that difference is, say, a 1% reduction in wound size overall, is the treatment worthwhile? Almost certainly not.

A better way is to find a subset of patients you can prospectively identify in whom the benefit of the intervention being studied is the greatest. **Note, the numbers in the following example are made up and for illustrative purposes only.** A study could find that 45 out of 100 (45%) patients heal with compression bandaging, while 55 out of 100 (55%) heal if compression bandaging plus a further intervention is used. Overall, the difference looks ok, but it could be made better and improve the chances of the intervention showing a statistically significant benefit. Let's say you could remove the 20% patients from each arm that would heal regardless of intervention and the 20% patients that simply wouldn't heal using a reasonable intervention in that setting. To make it simple, you screen these guys out prior to the study start, so that you still get 100 patients in each arm. The results of the study then become 63/100 (63%) compared to 77/100 (77%), respectively. The gap in performance between the two treatment arm has increased from 10% to 14% or **by 40%, overall**, making it much more likely a significant difference can be shown in favour of the additional intervention.

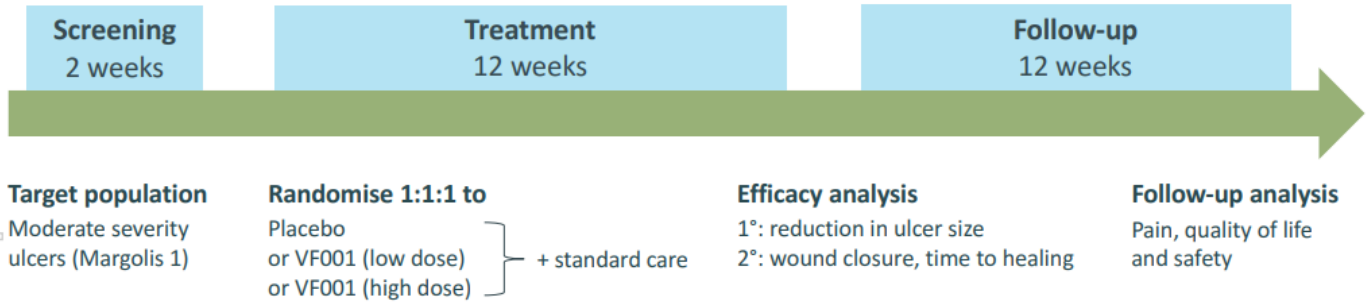
In its phase IIb study, Factor has incorporated a mechanism that they and we believe will act as an effective prospective screen to help ensure they are studying VF001 in a patient population in which they have the best chance of showing both a statistically and clinically significant benefit over compression bandaging alone. To do this, the phase IIb study trial was designed with a 2-week screening period built-in, prior to study enrolment, such that very fast healing ulcers do not enter the study. The study also only includes patients if the ulcers are:

- 2.5 cm^2 to not-more-than 5 cm^2 in area and 6 months or older
- Not-less-than 5 cm^2 to not-more-than 15 cm^2 in area and less than 6 months old

The two points described immediately above are part of a validated predictive VLU healing model developed by Margolis et al, where 1 point is given to a wound if it is greater than 5cm^2 in area and one point if the wound is greater than six months old (i.e.

wounds are scored on a scale of 0 to 2). The idea, of course, is to focus on Margolis 1 patients, where you find the highest percentage that would be on the borderline **of healing at 12 weeks**.

Figure 1. Phase IIb trial design of VF001 in venous leg ulcers.



Source: Factor Therapeutics Presentation, March 2018

We believe that Factor is the first and only company that has/is using the Margolis scale to enrich its study population in such a way and we believe it tips the trial in favour of a positive result for VF001

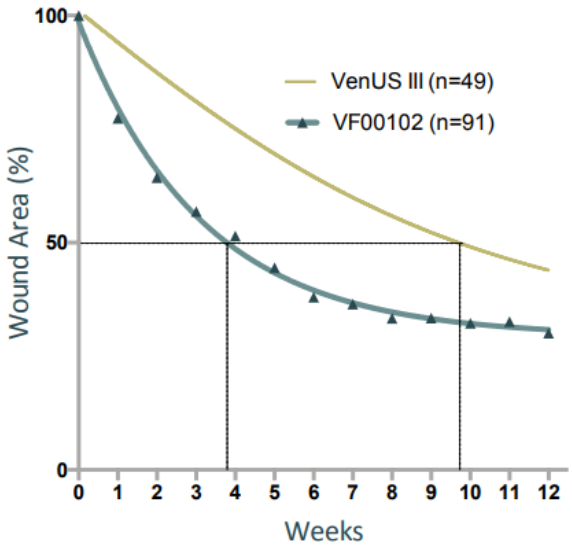
As a check on the likely usefulness of the Margolis score in its phase IIb study, Factor looked at its previously collected single arm trial data, which confirmed that the score did identify the group most likely to benefit from VF001 (Factor Therapeutics, Company Presentation, March, 2016).

The trial design is shown in figure 1 and its ClinicalTrials.gov identifier is NCT02973893. It is a double-blind, randomised, placebo-controlled trial in approximately 160 subjects, randomised 1:1:1, high dose VF001, low dose VF001 and placebo. All patients will receive uniform standard care with protocol-defined dressings and compression bandaging.

What We Know About the Trial Results

At its AGM in May of this year (2018), the company released the data contained in figure 2. It shows that in all patients (all treatment and placebo cohorts combined) overall wound size had reduced by 70%, with 53% of patients fully healed after 12 weeks of treatment. The historical control was derived from the VenUS III study (Health Technol Assess. 2011 Mar;15(13):1-192.) and shows a reduction in wound size of 55% and 41% of patients fully healed.

Figure 2. Data released by Factor Therapeutics regarding Its phase IIb study of VF001 in venous leg ulcers.



Source: Factor Therapeutics, AGM presentation, May 2018

The primary endpoint of the trial is the percentage reduction in the study ulcer area in each of the study groups over the 12-week treatment phase.

If one assumes that the placebo arm in the trial behaved as for the historical control, the combined result of the treatment arms would be an average 77.5% reduction in wound size. **This means that one or both of the different doses of VF001 would have reduced wound size by 10% or greater. A 10% difference is the approximate difference required in favour of VF001 for statistical significance to be shown** according to Factor. On that basis, the results so far look very good.

The big question, however, is whether you can trust the data from the historical control group. It is a subgroup of control patients from VenUS III, a large (n=337) study, which looked at the use of ultrasound to accelerate healing rates in VLUs. The subgroup selected for the historical control are those patients from the VenUS III standard of care arm who fit the inclusion/exclusion criteria as closely as possible to those Factor is using in its phase IIb trial.

Since little has changed in the treatment of VLUs between the VenUS III study, published in 2011, and today, the historical control used for the comparison does have some credence. Furthermore, the shape of the curve from Factor's VF001 IIb study has changed the way you would expect it to, if VF001 were causing the desired outcome, when compared to the historical control arm (i.e. the curve has become more concave and shifted to the bottom left hand corner of the graph). The sample size of the historical control is also, at least, like that of the placebo arm in Factor's trial.

Nonetheless, historical controls must be viewed warily, which is why randomised-controlled trials are almost always required by the FDA for a product approval, rather than trials that use historical controls.

A Solid Comparable Transaction

With all the estimates required to perform a probability adjusted discounted cash flow valuation of VF001/Factor, the value derived would likely be close to meaningless. Consequently, we have decided to focus deriving a value for VF001 based around a large, highly scrutinised, listed company and one of its equally highly scrutinised products, where we can be confident of highly efficient pricing by the market.

In 2012, Healthpoint Biotherapeutics was acquired by Smith & Nephew plc (SN; LSE: SN, NYSE: SNN) for USD782m (AUD819m, at the time). While Healthpoint was developing several products and had others on the market, the consensus was that the acquisition was primarily driven by S&N's desire to own HP802-247 (HP802), a cell-based therapy for VLU's. At the time of the acquisition, HP802 had completed a very successful phase II trial and just commenced, at least, one of two phase III studies.

Unfortunately for S&N shareholders, but fortunately for us, at 7am London time on October 13th, 2014, S&N announced to the market, via the London Stock Exchange, that HP802 had failed the first of two phase III trials in which it was being studied in the treatment of VLUs.

To value HP802, we have examined the decrease in S&N's market capitalisation for the trading day, the morning of which the trial failure was announced (i.e. 13/10/2014). To compensate for general market (systemic) risk, we have adjusted S&N's price movement by that of the FTSE 100 Index, of which S&N is a member, on the day. Additionally, there were no other announcements from S&N over the time period examined that could have impacted S&N's share price. Table 1 outlines our methodology.

Table 1. Derivation of the AUD decrease in S&N's value due to the first phase III HP802 trial failure announcement.

S&N Closing Price 10/10/2014	£9.910
S&N Closing Price 13/10/2014	£9.715
S&N Percentage Change	-1.46%
FTSE 100 Percentage Change	+0.42%
S&N Relative Percentage Change	-1.88%
S&N Market Cap Close 10/10/2014	£8,666,790,500
Adjusted S&N Overall Change in Value	£162,625,467
AUD Equivalent (13/10/14, GBP/AUD: $1.83)	**$298,287,631**

Source: Lodge Research & Estimates

While the value we have generated for HP802 seems intuitively solid, it is not a simple case of applying the value to VF001. Other factors that need to be considered are, but not limited to:

- The fact we have only measured the decline in value for the first of one of two phase III trials of HP802 for VLUs
- That manufacturing risk for HP802 was much higher than it appears to be for VF001
- Factor's unique phase IIb trial design
- That HP802 and VF001 are not strictly comparable in the population of VLU patients they are intended to treat
- S&N's expense on HP802's clinical trials
- The time value of money (this has not been considered for simplicity and conservatism)

The biggest issue in comparing the value we have derived for HP802 and VF001 is that, at the time of the first failure, HP802 was also involved in a second phase III trial, as per normal biologic development practice. Thus, the failure of one phase III trial did not spell the end of HP802 for VLUs and, hence, the fall in the value of S&N's shares does not fully reflect the complete value of HP802. For example, one report on the phase III failure quoted an Investec Ltd analyst as cutting his probability of success for the therapy from 50% to 25% (Reuter's Link Here). Investec is an international specialist banking and asset management group. Although, Lodge probably would have been harsher in reducing the probability of success, the Investec analyst did enjoy a different level of knowledge of HP802 than we have and was not operating with the same level of hindsight. If the Investec analyst were correct in his assessment, the true value of HP802 would have been **~AUD600m**, instead of the ~AUD300m given in table 1.

Unfortunately, S&N never announced to the market that they terminated the second phase III trial on February 23, 2015. Consequently, we can't use that trial termination to determine the remaining value the market saw in HP802.

VF001 & HP802 Manufacturing Difference is Significant

HP802 is also different to VF001 in that it is a cell therapy. Particularly, at the time that the first phase III trial result was announced, there were many doubts about how a commercial quality cellular therapy could be manufactured. We won't go into detail as to why this was the case but suffice to say that a root cause analysis to find the reason HP802 failed was found to be variation in the lot-to-lot therapeutic properties of the product (Wound Repair Regen. 2016 Sep;24(5):894-903. doi: 10.1111/wrr.12467.). VF001, as mentioned earlier, is simply two proteins conjugated (linked) together. Joining two molecules, as such, is routine these days and doesn't bear near the manufacturing and quality risk that does the reliable preparation of a cellular therapy. **Certainly, if HP802 had been as technically simple as VF001 to manufacture, its value would have been much higher and the market would have recognised this through a higher valuation.**

It also bears mentioning that VF001 manufacturing is pretty much already at a point almost certain to be acceptable to regulators. The reason for this is that the product has already been before regulators in Europe, when Factor's predecessor, the then Tissue Therapies, was attempting to gain approval for the product as a device. As stated earlier, European regulators denied VF001 approval specifically saying that they wanted to see safety data from a greater number of patients. The denial was unrelated to the quality and, specifically, the manufacturing data Tissue Therapies presented. **Had this been the case with HP802, unlike situation described in the previous paragraph, its value would certainly have been higher**.

The difference in manufacturing risk is the most difficult issue to deal with in terms of defining a differential value between HP802 and VF001. The obvious company with respect to manufacturing cellular therapies we thought to examine was TiGenix NV (EPA: TIG) and the manufacturing costs associated with their stem cell product for anal fistulae, Cx601. Cx601 recently gained marketing approval from the European Medicines Association. Unfortunately, the company's annual reports provided nothing concrete, although manufacturing risk, scale-up and transfer were consistently highlighted as key risks and it is intuitively clear that much was spent and remains to be spent on manufacturing development for Cx601, the latter as far as the scale-up to meet demand in the potential US market goes.

Mesoblast Limited (ASX: MSB), the world leader in developing adult stem cell therapies, is more transparent about its manufacturing costs than Tigenix and shares Lonza Group as its manufacturing partner. Over the last six years, Mesoblast has spent AUD193.0m (AUD/USD 0.734; USD141.6m) or an average of ~$32m per year on manufacturing development. The vast majority of those expenses are now behind it. While Mesoblast is clearly looking at a larger manufacturing scale than Tigenix, given the number of products Mesoblast has in late stage development, those products are all built off very similar, if not identical, processes, so simply dividing Mesoblast's manufacturing costs by the number of products in development isn't appropriate. It does seem reasonable to assume that TiGenix NV, plus its new owner Takeda Pharmaceutical Company Limited (TSE: 4502), would have and need to spend $100m to $125m, if not more, to get manufacturing completely up to speed. Assuming a spend of $25m by manufacturing spend by Factor, **we come up with a value of $75m to $100m favouring VF001 in terms of reduced manufacturing risk**.

Probability of Success, Market Differences & Clinical Trial Spend

Earlier, we discussed our views on the unique phase IIb trial design Factor is using with VF001. **We have pegged the chance that VF001 will return a positive result in this trial at 65%**. This probability is very much intuitively derived from our knowledge, general and specific, related to clinical trial success rates and VF001.

From a marketing perspective HP802 was intended to treat the roughly 4% of patients with VLUs that simply don't heal with standard therapy. Obviously, this represents a much smaller market than Factor is targeting with VF001. The flip-side is that insurers would be likely to agree to pay more for HP802, than for VF001, on a case-by-case basis, because referred patients would be in worse condition than those VF001 is aimed at and healing the ulcer would save more money for the insurer. Exactly how this would balance out is not clear and will probably depend very much on the data each could have put forward to insurers to support their pricing. Obviously, this is an outcome HP802 will never see and one that VF001 is a way away from seeing. Having said that, again, because VF001 came so close to approval in the EU as a device, we believe they have gathered and continue to gather robust data to support the pricing of the product. **Overall, we tend to think that the differences between the products are broadly likely to cancel each other out and view the issue as neutral in terms of valuation.**

As a clinical trial progresses, the cash the company spends on it should shift from cash in the bank to the value of the product it is being spent on, in a fairly value neutral way. Thus, any value we derive for HP802 should consider how much S&N spent on it to get it to the end of the first phase III trial. We have scoured S&N's accounts but have been unable to gain any clarity on what that actual value might be and using the expected cost from Factor's phase IIb trial probably isn't much help either. In general, smaller companies, like Factor, don't have the internal assets from which synergies can be extracted nor do they have the same negotiating power as larger companies, like S&N, when negotiating with clinical trial research organisations that often conduct the trials. Simply based on our knowledge of clinical trial costs, we would put **a value of ~$50m to ~75m on S&N's costs**.

Expressing VF001 Value as an Equation

The equation we come up with to derive a value for VF001, looks like this (table 2):

Table 2. Expression of the value of VF001 as a function of the factors discussed.

Value (AUD)		Value HP802 First Phase III Failure		Value HP802 Second Phase III Failure		VF001 Phase II Probability of success		Value of Manufacturing risk		Value of Market Differences		S&N Trial Costs
VF001	=	$300m	+	Up to $300m	+	65%	+	$75 to $100m	+	Neutral	-	$50m to $75m

Source: Lodge Research & Estimates

Valuation

To provide an estimate of the net present value (NPV) for VF001, **we start with a base of $300m**, derived from the effect of the failure of HP802 in its first phase III clinical trial on S&N's share price. We would have reduced HP802's chances of success by more than the 50% Investec did. We think a range of 15% to 20% (as opposed to Investec's 25%) to be a better estimate and we have used the mid-point of 17.5% in our final calculation, which contributes **$210m to our valuation**.

To reflect the discrepancy, the value of manufacturing risk and S&N's contribution to trial costs, **we have simply added a further $25m to the value of VF001**.

Ultimately, we arrive at a value of **AUD535m for VF001 if it returns a positive phase IIb trial result**. As a reminder, this result is due in Q4 of this calendar year.

Once we apply our 65%% probability of success for VF001 in its phase IIb trial, **we arrive at a present value for VF001 of $348m**.

Using Factor's **fully diluted number of shares** in the company listed on the front page of this report, we calculate a value for the VF001 program **of 33.5 cents per share prior to the phase IIb result and a price of 52 cents per share should the phase IIb result prove positive**.

The current share price of 6.0 cents gives Factor a fully diluted market capitalisation $62.3m. Based on this and our estimated value of the VF001 program after a positive phase IIb result of $525m, it suggests that the market is factoring in only a 11% to 12% chance of the trial returning a positive result. To illustrate how out of touch this is with the general probability of success in the literature for phase II trials, most experts put the probability of success of this type of trial at between 30% and 40%. Using these numbers, Factor should be worth 3 to 4 times its current share price, irrespective of the quality of the previous data produced with the drug, how well the phase IIb study is designed or how well run the study has been.

Conclusion

We are using VF001, as stated, as a proxy for the entire value of Factor. While Factor does have other earlier stage programs, we feel disregarding them in our valuation is simply responsible.

We have used an unusual method for estimating the NPV of Factor's shares. While the valuation is based on a very close look at a single transaction, the value we have derived is intuitively reasonable based on our general knowledge of valuations for phase II companies worldwide and it fits with the view expressed by others at the time that HP802 was the driving factor behind S&N's decision to acquire Healthpoint. Importantly, S&N and the HP802 program were and the former still is under intense investor scrutiny, given S&N is a large company (Mkt Cap: AUD21.2b; AUD/GBP: 0.56) it is likely to be very efficiently priced.

It is difficult to see FTT's share price racing to our calculated NPV before the trial results or toward the higher value if the phase IIb results are positive, until a trade sale or licencing offer is on the table. Still, our valuation of the FTT shows that there is an enormous amount of upward movement that can occur before the price starts to look even close to strained.

We believe FTT's share price is likely to move upward, as we near the phase IIb clinical trial result in Q4. The price is also likely to move upward when the company falls on the radars of specialist investors, predominately from the US, as has happened with Clinuvel Limited (ASX: CUV), Opthea Limited (ASX: OPT) and Viralytics (formerly, ASX: VLA). Despite the probability of success, we have placed on the VF001 phase IIb trial, the big jump in value is likely to occur once a solid licencing deal or buyout is on the table. Provided positive phase IIb results, **we see such a deal being made in the latter half of next CY (i.e. 2019) and we believe it will likely be a take-out offer**, given a positive VF001 result will have proved up the technology for further indications and the fact that, without outstanding licences or other conflicting factors, Factor would represent a clean take-out target.

Recommendation

We have calculated an NPV for Factor Therapeutics of 33.5 cents per share on a fully diluted basis prior to the phase IIb trial results due at the tail-end of this year. Should the VF001 phase IIb trial results prove positive, we estimate an NPV of 52 cents per share. While the numbers highlight the enormous upside in the stock, they do not reflect 12-month price targets, as such, and we are not placing that type of target on the stock. Having said that, given the potential catalysts and the likelihood they go in Factor's favour over the next 6 to 18 months, **the company is an extremely compelling buy and we rate it as such**.

Factor Therapeutics

Just Quality Biotech with Significant Near-Term Catalysts

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Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into three main categories:

Buy: Expected Total Return more than 15% over a 1-year period.

Hold: Expected Total Return between 0% and 15% over a 1-year period.

Sell: Expected Total Return less than 0% over a 1-year period.

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The analyst owns 100,000 shares in the company mentioned in the report.

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