

# Immix Biopharma

Fresh faces with a unique tissue-targeting therapy

Initiation of coverage

Pharma and biotech

19 September 2022

**Price** **\$1.73**  
**Market cap** **\$24m**

Net cash (\$m) at 30 June 2022 18.4  
 Shares in issue 13.9m  
 Free float 42%  
 Code IMMX  
 Primary exchange Nasdaq  
 Secondary exchange N/A

## Share price performance



%	1m	3m	12m
Abs	(26.1)	(26.4)	N/A
Rel (local)	(18.6)	(28.5)	N/A
52-week high/low		\$6.75	\$1.3

## Business description

Immix Biopharma is developing a new class of tissue-specific therapeutics targeting oncology and immune-dysregulated disease. In Q422, the company's lead clinical asset, IMX-110, is expected to begin a Phase IIa study for the treatment of STS and a Phase 1b trial in advanced solid tumours in combination with the ICI tislelizumab. The company also has a preclinical pipeline based on the TSTx technology.

## Next events

Phase II trial STS initiation	Q422
Phase I IMX-110 combination trial initiation	Q422

## Analysts

Soo Romanoff	+44 (0)20 3077 5700
Dr Harry Shrivess	+44 (0)20 3077 5700
Dr Adam McCarter	+44 (0)20 3077 5700

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)

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**Immix Biopharma is a research client of Edison Investment Research Limited**

Immix Biopharma is a clinical-stage biopharmaceutical company focused on the development of its SMARxT tissue-specific platform producing Tissue-Specific Therapeutics (TSTx). Its lead clinical asset, IMX-110, is being investigated for the treatment of soft tissue sarcoma (STS), where interim results from its [Phase Ib](#) trial have, so far, demonstrated positive safety and efficacy profiles, albeit in a small patient population. Management now intends to initiate Phase IIa of the study in first-line STS in Q422. We also expect a Phase Ib study of IMX-110 in combination with tislelizumab (an anti-PD-1 antibody) to begin in Q422. To support this trial, Immix has entered a supply agreement with BeiGene. Immix had a net cash position of US\$18.4m at end-June 2022, which we estimate will fund operations to Q424. We value Immix Biopharma at US\$56.7m or US\$4.1 per share.

Year end	Revenue (US\$m)	PBT* (US\$m)	EPS* (US\$)	DPS (US\$)	P/E (x)	Yield (%)
12/20	0.0	(0.56)	(0.51)	0.0	N/A	N/A
12/21	0.0	(1.31)	(0.36)	0.0	N/A	N/A
12/22e	0.0	(6.09)	(0.44)	0.0	N/A	N/A
12/23e	0.0	(8.78)	(0.63)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

## A novel, targeted drug delivery platform

Immix Biopharma's development programme is currently focused on IMX-110. We believe the drug's unique targeted design could offer market differentiation over existing standard of care (SoC) regimens in certain cancers. Management expects to initiate Phase IIa of the study in first-line STS with IMX-110 in Q422, given that the Phase Ib trial demonstrated positive interim safety and efficacy data. IMX-110 will also be investigated in combination with tislelizumab in solid tumour indications (Phase Ib expected to commence in Q422). We see this as potentially lucrative as the combination may offer differentiation in the competitive immune checkpoint inhibitor (ICI) space.

## Targeting accelerated approval but licensing deal key

Management expects data, if positive, from the Phase IIa trial in STS will support an FDA accelerated approval application in the United States, given the unmet medical need in this indication. However, we see a licensing deal as crucial to maximise IMX-110's commercial impact. In our view, an existing collaboration with BeiGene to provide its ICI drug tislelizumab could provide the company with strategic development advantages and the possibility of a licensing deal, should clinical results prove positive.

## Valuation: US\$56.7m or US\$4.1 per share

We value Immix Biopharma at US\$56.7m or US\$4.1 per share. Our valuation is based on a risk-adjusted NPV calculation for IMX-110 in STS and solid tumour indications and incorporates a net cash position of US\$18.4m at end-June 2022. We estimate the company's current cash position will fund operations to Q424.

## Investment summary

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### Company description: Two clinical catalysts in FY23

Founded in 2012 and listed on the Nasdaq in December 2021, Immix Biopharma is an early-stage, US-based biotechnology company focused on the development of TSTx produced by its SMARxT tissue-specific platform. The company's lead asset, IMX-110, uses negatively charged TSTx encapsulating a synergistic combination of poly-kinase inhibitor (polyphenol curcuminoid complex, or PCC) and apoptosis inducer (PEG-PE doxorubicin complex) that delivers drugs specifically to tumour sites, inhibiting multiple kinases and interfering with NF-κB and STAT3 activation, interrupting the cancer-sustaining inflammatory cycle. Preliminary results from the ongoing Phase Ib trial of IMX-110 ([NCT03382340](#)) demonstrated promising safety and efficacy profiles in a subset of enrolled patients. The company is now preparing to start the Phase IIa portion of this trial in STS. We note that Phase Ib data were collected from a small subset of the trial population and the results should therefore be generalised with caution. Management expects that rolling data readouts from the Phase IIa trial (expected to begin enrolment in Q422) over FY23 and FY24 (with full results expected in Q424) could form the basis for accelerated approval in the United States, if positive. We believe these data readouts could be significant near-term catalysts for the company.

Immix is also preparing to initiate a Phase Ib dose finding study of IMX-110, in solid tumour indications, in combination with BeiGene's ICI tislelizumab. The study is expected to begin in Q422 and will be run under a clinical trial supply agreement for tislelizumab with BeiGene, which we believe provides a significant strategic advantage for the company. We expect Immix will pursue a development/commercialisation licensing deal for IMX-110, assuming positive readouts.

### Valuation: US\$56.7m or US\$4.1 per share

We value Immix Biopharma at US\$56.7m or US\$4.1 per share. Our valuation is based on a risk-adjusted NPV calculation for IMX-110 in STS (rNPV US\$26.9m or US\$1.9 per share) and solid tumour indications (rNPV US\$11.4m or US\$0.8 per share) and incorporates a net cash position of US\$18.4m at end-June 2022. In our valuation we apply a discount rate of 12.5% and assume a full licencing deal for IMX-110 is attained in mid-2025, after results from the combination and monotherapy studies. Additionally, we apply a probability of success of 15% to IMX-110 monotherapy in STS and 10% in solid tumour indications.

### Financials: Development funded to Q424

After listing on the Nasdaq in December 2021 (raising net proceeds of US\$18.65m), the company reported a cash position of US\$18.40m at end-H122 with no debt. We anticipate a large rise in R&D expenses to FY24 as clinical activities increase. The company reported R&D expenses in H122 of US\$1.24m and a cash burn rate of US\$2.04m; therefore we estimate the company's operations are funded to Q424. Past this, we anticipate the company will need to raise additional capital to support operations until a licensing deal for IMX-110 can be found, which we estimate to be in mid-2025. Management has communicated an R&D budget of [US\\$11m](#) for the development of IMX-110 in two clinical trials, [significantly below industry averages](#).

### Sensitivities: Pureplay biotech risks

Immix Biopharma is subject to the regular risks associated with drug research and development. As a pureplay biotech, the company will be affected by development delays or failures, regulatory risks, competitor successes, partnering setbacks and financing risks. The largest development sensitivities relate to the company's lead clinical asset, IMX-110. The most prominent near-term risk would be failure to demonstrate clinical proof-of-concept in its upcoming Phase IIa trial. While the

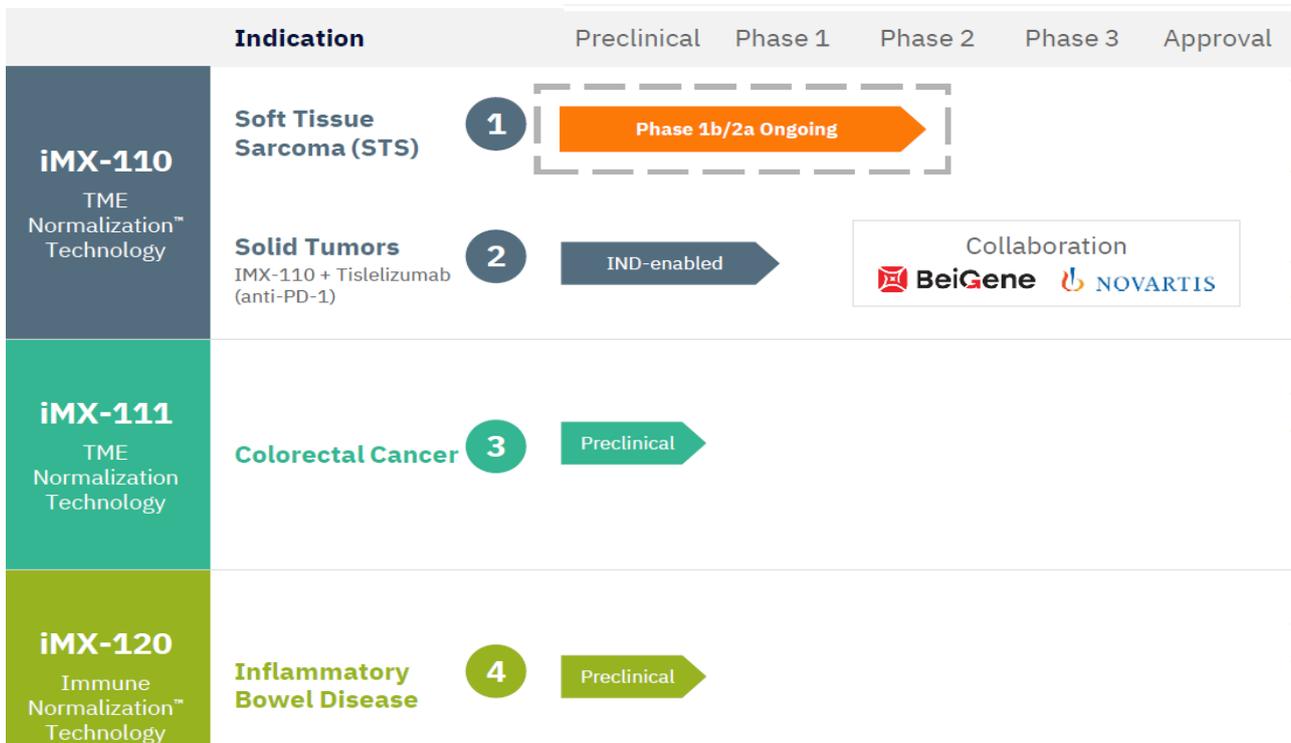
company has reported encouraging interim trial readouts with IMX-110, data was collected from a small, heavily treated patient group. First-line patients, the target population for Phase II development, may exhibit significantly different responses.

## Company description: Scaling up IMX-110 clinical data in STS and in combination with Novartis’s PD-1

Immix Biopharma’s clinical development strategy is primarily focused on IMX-110. Data from the company’s ongoing Phase Ib ([NCT03382340](#)) dose finding study has allowed the commencement of preparations for the Phase IIa proof-of-concept stage of this trial (expected to begin Q422) investigating the use of IMX-110 as a first-line treatment for STS. In a second approach, Immix Biopharma will assess IMX-110 in combination with the anti-PD-1 ICI tislelizumab (BeiGene) in solid tumour indications. The Phase I study is expected to begin in Q422 and will be coordinated through a collaboration between Immix Biopharma and BeiGene. We believe this is a favourable development as combinational therapy approaches could potentially open future development and/or licensing opportunities. Additionally, the benefit of combinational therapy regimens is becoming increasingly relevant in oncology (see our Edison [prospectus](#) on the oncology landscape).

The company also has two preclinical assets, IMX-111 and IMX-120. Like IMX-110, IMX-111 and IMX-120 are built on its SMARxT tissue-specific platform, and are in preclinical development as potential treatments for the large-market indications colorectal cancer and inflammatory bowel disease, respectively.

**Exhibit 1: Immix Biopharma R&D pipeline**



Source: Immix Biopharma corporate presentation

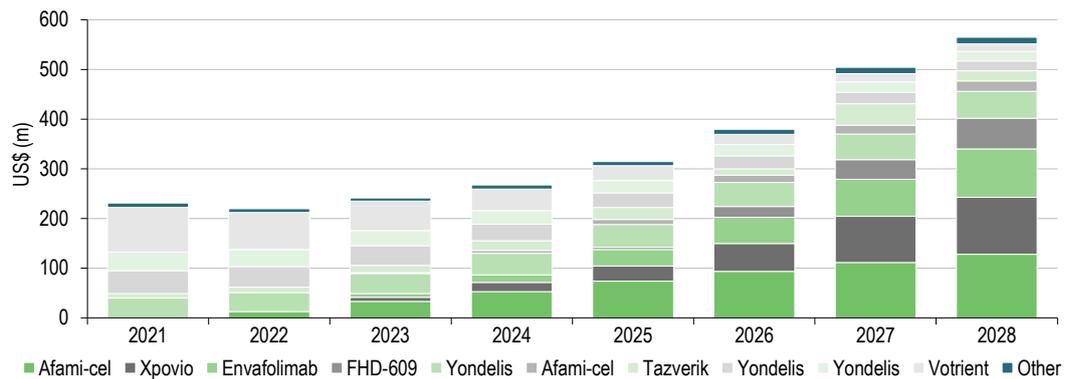
### Targeting rare cancers

STS is a rare type of cancer affecting the tissues that connect, support and surround other body structures and organs. In the United States, 13,190 people will be diagnosed with STS in [2022](#) with

an expected 5,130 deaths. There are approximately 160,079 people living with STS in the US. In [Europe](#), approximately 21,500 people are diagnosed with STS each year.

In STS, the current first-line SoC is doxorubicin, a chemotherapy agent that suffers from low response rates and limited utility due to off-target toxicity. Immix Biopharma aims to address these problems through IMX-110's unique tumour-specific delivery mechanism. We believe the lack of safe, tolerable and effective therapies in STS represents a significant unmet medical need. Additionally, EvaluatePharma estimates that the market for STS treatment will reach US\$565m by 2028 and is highly fragmented, which we believe provides an opportunity for Immix Biopharma as it may be able to garner significant market share, including potentially IMX-110 as a first-line therapy.

**Exhibit 2: Estimated STS market to 2028**



Source: EvaluatePharma

IMX-110 has [received](#) orphan drug designation (ODD) for the treatment of STS as well as rare paediatric disease [designation](#) (RPDD) by the US FDA for the treatment of rhabdomyosarcoma, another type of rare soft tissue cancer in children. An RPDD qualifies Immix Biopharma to receive fast track review, and a priority review voucher (PRV), upon approval of IMX-110. A PRV entitles the holder to an expedited six-month review of a new drug application by the FDA. Notably, PRVs are tradable assets that regularly fetch upwards of [US\\$100m](#) in value.

Several market-leading ICIs are currently in clinical development targeting STS, primarily in combination with another treatment, including Merck's pembrolizumab (Keytruda, [Phase II](#)), Bristol Myers Squibb's nivolumab (Opdivo, [Phase II](#)) and Roche's atezolizumab (Tecentriq, [Phase II](#)). The potential expansion of approval into STS of any of these drugs, we believe, would have a profound impact on the shape of the market and competitive landscape. However, we believe positive results from these studies may be beneficial for Immix, as the company is also investigating IMX-110 in combination with ICI therapies.

We note that annual sales of Merck's pembrolizumab (Keytruda) and Bristol Myers Squibb's nivolumab (Opdivo) are [\\$17bn](#) and [\\$7.5bn](#), respectively, representing significant market potential for IMX-110 in combination with ICI therapies in further indications.

## Future partnerships key for success

The company expects rolling interim readouts from the key Phase IIa study of IMX-110 in STS throughout FY23, which will be critical in establishing the drug's clinical utility. We believe a licensing deal will be key for further clinical development and eventual commercial success of IMX-110, particularly as the asset advances into subsequent capital-intensive clinical trials. While clinical partners are yet to be identified, we expect the company's collaboration with BeiGene may open opportunities for future licensing deals should clinical efficacy be demonstrated.

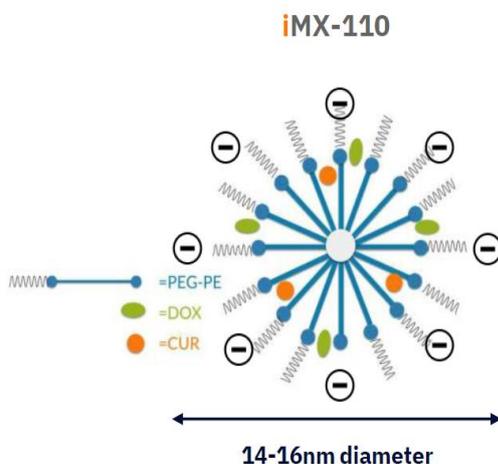
## Structured patent strategy

Immix Biopharma possess an extensive global patent portfolio consisting of 11 granted US and foreign patents, four pending US and foreign patent applications and two provisional US patent applications related to its TSTx platform and product line. The company's strategy is to create multi-layered IP protection, which covers formulations, manufacturing methods, methods of use and functional characteristics of its product candidates. Importantly, Immix Biopharma's granted US patent for the treatment of cancers with its micellular technology ([US 2015O110877A1](#)) is expected to provide market protection for IMX-110 until 2033. IMX-110 has also been awarded an ODD, securing the company a minimum of seven years market exclusivity in the United States.

## IMX-110: Surrounds and conquers by pulling the plug on cancer

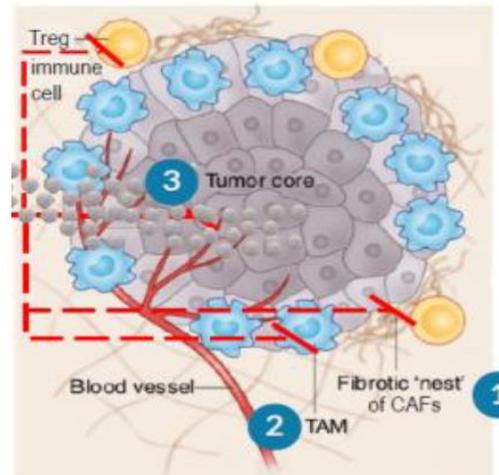
Solid tumour growth is supported by new blood vessel formation initiated through [inflammatory signals](#) (cytokines and others) induced by tumour hypoxia and acidosis. This hypoxia and acidosis upregulates NF-κB, STAT3 and other transcriptional factors causing a sustained immuno-dysregulated environment. This immuno-dysregulated environment is called the tumour microenvironment (TME) and is made up on a packed mass of three components: 1) cancer-associated fibroblasts (CAFs), 2) tumour-associated macrophages/immune cells (TAMs) and 3) cancer itself. The TME feeds and sustains the tumour. Management believes that all three components of the TME must be addressed to treat the tumour and that conventional therapies have been hampered by resistance caused by NF-κB and STAT3 activation.

Exhibit 3: IMX-110



Source: Immix corporate presentation

Exhibit 4: TME targeted by IMX-110



Source: Immix corporate presentation

IMX-110 contains two active payloads, a poly-kinase inhibitor (PCC) and apoptosis inducer PEG-PE doxorubicin. Management asserts that this combination targets all three components of the TME: CAFs, TAMs and the cancer cells themselves, as shown on Exhibit 4. CAFs regulate tumour occurrence and therapeutic resistance, while TAMs are key cells involved in creating an immunosuppressive TME.

IMX-110's potential to deliver its poly-kinase inhibitor to all three components of the TME is designed to disrupt the essential physiological network between the tumour and its metabolic and structural support, inhibiting multiple kinases and interfering with NF-κB and STAT3 activation ('surround'), resulting in cancer cell death and tumour shrinkage.

With tumour-sustaining inflammation halted, IMX-110's apoptosis inducer is then able to induce tumour cell death where conventional therapies have been hampered by resistance caused by NF- $\kappa$ B and STAT3 activation ('conquer').

We note that targeted therapies often offer the potential to widen the therapeutic window, meaning larger doses of drugs can be used with a potentially safer profile. The company has not yet confirmed IMX-110's ability to do this. However, we see it as a possibility that management could choose to investigate.

**Exhibit 5: IMX-110's three key characteristics**

**01**  
iMX-110: First Oncology Micelle to achieve "small molecule penetration"

**12nm Diameter Nanoparticles Demonstrate Superior Mouse Tissue Penetration (vs. 60nm, 125nm)**

(Adapted from Popovic et al, 2010)

HD = 12nm    HD = 60nm    HD = 125nm

**02**  
Electrostatic charge attracts to tumor like a magnet

**Micellar DOX (<40nm) Selectively Accumulates in Mouse Tumor vs. Free DOX**

(Adapted from Yokoyama et al, 1999)

"Biodistribution analysis revealed that the physically entrapped micellar ADR accumulated at tumor sites in a highly selective manner"

**03**  
Resulting in 1,200% increase in apoptosis (tumor cell death) vs. conventional therapies

**Caspase 3/7 Increase (%) vs. Control (empty micelle) as an indicator of tumor apoptosis, after 24h**

Control: 1%    Free DOX: 15%    DOX micelles: 35%    CUR micelles: 53%    iMX-110: 181%

**1,200% increase**    **181%**

3D Spheroid Glioblastoma U87MG cells were treated with 0.1  $\mu$ M DOX and 20  $\mu$ M CUR in micellar formulations for 24 h, followed by the Apo-ONE Homogeneous Caspase-3/7 Assay. Results were normalized against the control group and presented as mean  $\pm$  SD.

(Adapted from Sarisozen et al, 2016)

Source: Immix corporate presentation

Immix Biopharma's IMX-110 has three key unique characteristics: first, it is the first micelle with 'small molecule penetration', which allows it to exit perforated tumour blood vessels en route to the tumour, second, IMX-110's negative charge allows it to be pulled into the tumour like a magnet and third, IMX-110 induces 1,200% more cancer cell apoptosis (or cell death) than conventional therapies (see Exhibit 5).

[Clinical data to date](#) have highlighted this, with IMX-110's TSTx demonstrating favourable safety and early signs of efficacy profiles over free dosage forms of conventional chemotherapy agents.

**Poly-kinase inhibitor + apoptosis inducer: A winning combination?**

We believe IMX-110's poly-kinase inhibitor PCC can be related to curcumin in the literature. Curcumin has been [shown](#) to inhibit various resistance-related pathways in cancer cells as a multikinase inhibitor. However, its clinical use in oncology has been restricted due to its poor physicochemical [properties](#) such as light sensitivity and low solubility in water. We note that curcumin has shown [signs of efficacy](#) in combination with chemotherapy in a Phase IIa metastatic cancer study in the UK. Patients treated with a combination of FOLFOX chemotherapy and curcumin recorded a median overall survival of 502 days versus 200 days for FOLFOX alone. While

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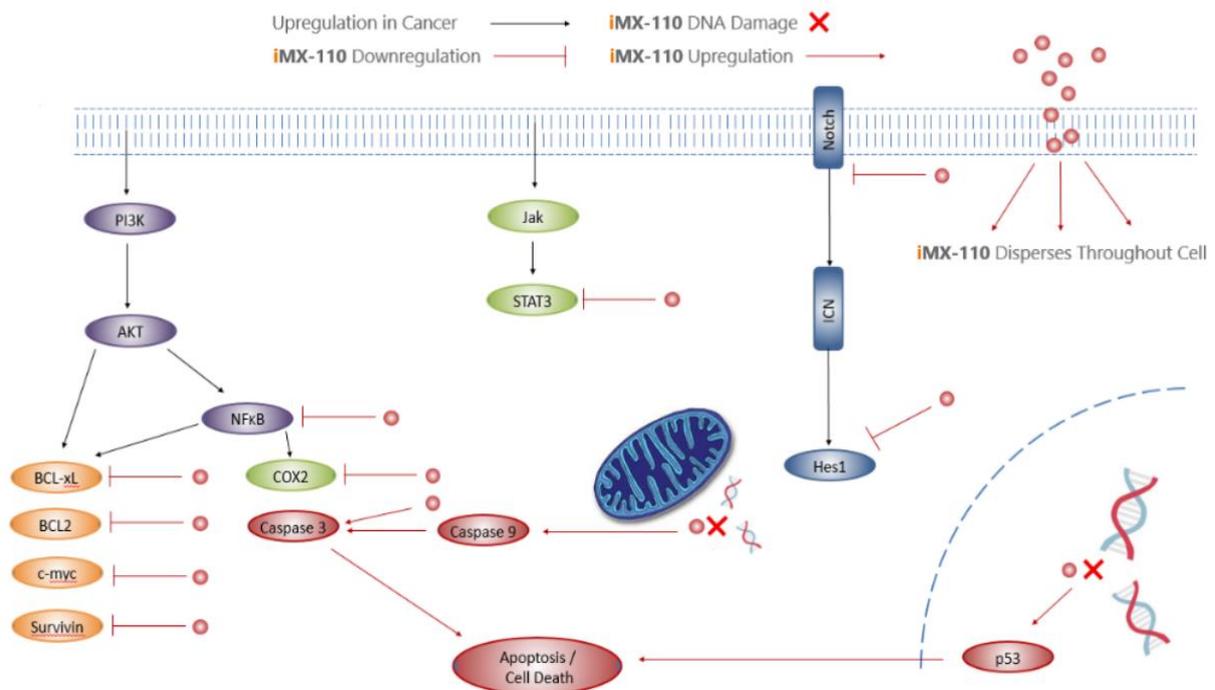
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this demonstrates proof of concept efficacy, we note that such studies have not been widely repeated.

IMX-110's apoptosis inducer PEG-PE doxorubicin complex can be related to doxorubicin in the literature. Doxorubicin is believed to target cancer cells through several different mechanisms: it can disrupt the structure of DNA (intercalation), inhibit topoisomerase II (a protein essential to DNA replication and cellular mitosis) and cause direct oxidative damage to DNA. However, as mentioned, doxorubicin's use is limited by potentially severe off-target side effects (including cardiotoxicity) and pre-existing or acquired tumour resistance.

IMX-110's dual action mechanism has potential to increase the overall cytotoxicity of IMX-110 (as shown by Immix, where IMX-110 produced a 1,200% increase in apoptosis versus conventional therapies in a preclinical cancer model). When released into the target cells, doxorubicin causes DNA damage, resulting in the upregulation of p53 and triggering of apoptosis (cell death). Curcumin interrupts the (PI3K)/Akt signalling pathway, a major survival pathway in cancer cells. The inhibition of NF-κB by curcumin results in downregulation of the (PI3K)/Akt pathway, which is another trigger that leads to cellular apoptosis (see Exhibit 6).

### Exhibit 6: IMX-110 mechanism of action



Source: Immix Biopharma corporate presentation

## IMX-110: The story so far

### Early yet encouraging data in STS

Immix Biopharma's ongoing Phase Ib trial of IMX-110 as a monotherapy is currently being conducted in Australia and the United States, and to date has treated 14 patients (Phase Ib estimated full recruitment n=30). This is an open-label, dose escalation (3+3) study designed to assess the safety and tolerability of IMX-110 as a monotherapy in patients with STS and non-sarcoma advanced solid tumours. Out of 14 patients, eight were evaluable at the time of analysis, with four patients harbouring STS. The six non-evaluable patients did not complete any tumour measurements after treatment with IMX-110, independent of safety. All patients had undergone at

least three lines of previous therapy including chemotherapy and immunotherapy. Preliminary data from the STS patient cohort (n = 4), the indication of focus in the upcoming Phase IIa portion of the study, are shown in Exhibit 7.

Exhibit 7: Phase Ib data in comparison with other treatments used to treat STS								
Drug	Line of treatment	STS sub-indication	Disease control (stable disease) after two months	mPFS	Dose interruptions due to toxicity	Drug-related SAEs	Overall response rate	Source
Doxorubicin	1st line	Leiomyosarcoma	68%	2.7 months	No data	18%	0%	<a href="#">Chawla et al, 2015</a>
Trabectedin	2nd line	Liposarcoma	62%	4.2 months	57%	13%	10% (0% CR)	<a href="#">Demetri et al, 2015</a>
Eribulin	3rd line	Liposarcoma	58%	2.6 months	33%	8%	4% (0% CR)	<a href="#">Schöffski et al, 2016</a>
<b>IMX-110</b>	<b>Median 7th line (4–14th line)*</b>	<b>Leiomyosarcoma/ liposarcoma/ undifferentiated pleomorphic sarcoma</b>	<b>100%</b>	<b>4 months</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>	<a href="#">Immix Biopharma</a>

Source: Chawla et al, Demetri et al, Schöffski et al, Immix Biopharma corporate presentation. Note: STS = soft tissue sarcoma, mPFS = median progression free survival, SAEs = serious adverse events, CR = complete response. \*Represents collective data from all four pre-treated (4–14 lines) evaluable STS patients.

Of note, IMX-110 reported 100% disease control (stable disease after two months) in four STS patients after two months and no dose interruptions of drug-related SAEs. This translated into a positive impact on progression-free survival (PFS), which was improved or maintained versus reported competitor data. Interestingly, one patient, who had been heavily pre-treated (13 lines), recorded a six-month PFS again with no safety concerns. Management is particularly encouraged by this result as, presumably, such a patient would have developed significant resistance to treatment and/or would have experienced serious decline due to 13 prior lines of treatment. Altogether, IMX-110 displayed improved PFS and safety over first-line treatment (doxorubicin). Additionally, IMX-110 was found to demonstrate broad activity over a range of STS subtypes and, to date, all patients enrolled in the trial have [completed](#) their planned treatment cycles without reporting safety concerns. In our view, the [overall response rate](#) (ORR) is not a clinically relevant metric to assess the efficacy of IMX-110 against as historical doxorubicin ORR rates have remained at 0%. Of greater importance, we believe, are disease control (stable disease) and median progression-free-survival data points, the results of which are potentially significant compared to doxorubicin alone (based on historical doxorubicin data as shown in Exhibit 6).

While we recognise that this preliminary data in STS represents a small patient sample, collectively, we see the improved efficacy and safety profile demonstrated by IMX-110 over existing SoCs as a positive result. We believe the broad application across STS subtypes is also encouraging and may provide further diversification for IMX-110 in the STS treatment market. The Phase IIa expansion of this study into first-line STS, intends to recruit an additional 30 patients (hence the Phase Ib and Phase IIa portions of the study plan to enrol 30 patients each, for total enrolment of c 60 across both portions) with the first expected to be dosed in Q422. Rolling interim data readouts are expected in H123. We anticipate top-line results to be announced at end-FY24. These results, in our view, will be crucial in establishing IMX-110's clinical utility, not only in STS but also potentially in other monotherapy and combination indications.

## Anti-PD-1 combination next on the horizon

The company expects Q422 will see the commencement of a Phase Ib trial investigating the use of the IMX-110 in combination with tislelizumab. The single-arm, dose-escalation (3+3) study aims to assess the safety and tolerability of the combination in patients (estimated n=30) with advanced solid tumours. The trial will determine the maximum tolerated dose and recommended Phase II dose for evaluation in the Phase IIa study. Management's intention is to provide rolling data readouts throughout FY23 and FY24. In our opinion, the initiation of an ICI combination study is a

positive step in the clinical development of IMX-110, with multi-drug oncology treatment regimens often demonstrating [synergistic interactions](#) and improved efficacies.

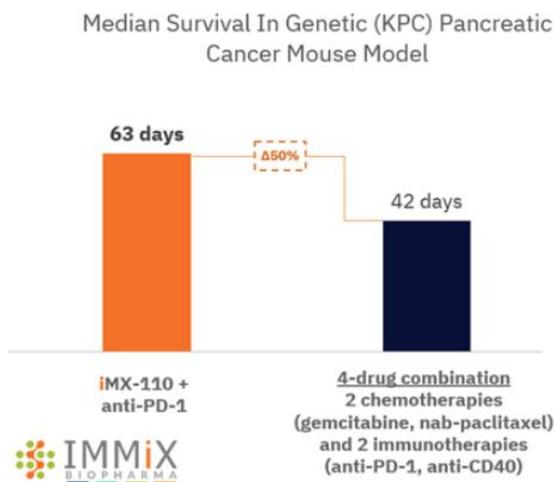
### PD-1 combination holds potential

In August 2021, Immix Biopharma [announced](#) it had entered into a manufacturing and supply agreement with BeiGene for the anti-PD-1 antibody tislelizumab as part of a combination study with IMX-110. Tislelizumab has so far been [approved](#) or granted conditional approval in nine cancer indications in China, including non-squamous non-small cell lung cancer (NSCLC), squamous NSCLC, classical Hodgkin's lymphoma, hepatocellular carcinoma and urothelial carcinoma. The drug was [in-licensed](#) (for an upfront payment of US\$650m, up to US\$1.55bn in milestone payments plus royalties) by Novartis in February 2021, granting the company the right to develop, manufacture and commercialise the anti-PD-1 outside of China. However, tislelizumab's success outside of China has been limited, with Novartis [recently scrapping](#) a US approval application for its use in NSCLC. Considering this, we believe that any differentiation in safety and/or efficacy that the tislelizumab/IMX-110 combo can demonstrate versus tislelizumab monotherapy could be valuable for Novartis and may open potential licensing deal negotiations. Establishing development partnerships for drug combination trials can often be lengthy and complex, so this collaboration, in our view, could give Immix a significant strategic advantage with the potential to expand the IMX-110 development programme to further indications.

### Combination supported by preclinical studies

In Q122 Immix Biopharma [announced](#) preclinical data that provided an encouraging clinical rationale for the planned combination trial. The mouse model data saw an improvement in median survival by c 50% in mice treated with IMX-110 in combination with an anti-PD-1 inhibitor (ICI) compared to those treated with a four-drug combination therapy, which included two ICIs, Exhibit 8. While we see this data as encouraging, we note that preclinical results are not necessarily a reliable indicator of clinical utility.

**Exhibit 8: Preclinical IMX-110 data in combination with anti-PD-1**



Source: [Immix Biopharma press release, January 2022](#)

### Preclinical assets in FY23

While IMX-110 is the primary focus of Immix Biopharma's portfolio, the company is also developing two other assets that are currently in preclinical studies. IMX-111 and IMX-120 both utilise the same TSTx technology platform as IMX-110, with modified targeting components. IMX-111 and IMX-120 build on IMX-110 with the inclusion of a GLUT1 targeting antibody and are being assessed for the treatment of colorectal cancer and inflammatory bowel disease, respectively. Preclinical studies are

expected to be completed by the end of 2022, with the intention of filing investigational new drug applications to the FDA in H223.

## Sensitivities

Immix Biopharma is subject to the regular risks associated with drug research and development. As a pureplay biotech, the company will be affected by development delays or failures, regulatory risks, competitor successes and financing risks. The largest development sensitivities relate to the company's lead clinical asset, IMX-110. The most prominent near-term risk would be failure to demonstrate clinical proof-of-concept in the upcoming Phase IIa portion of the IMX-110 STS monotherapy trial. Early clinical data from IMX-110's ongoing Phase Ib study have been encouraging; however, they only represent a small STS patient cohort, which does not ensure clinical success. This low percentage of evaluable patients compared to the total treated makes interpretation of these results challenging. As a drug developer, Immix Biopharma is a highly cash consumptive business and may need to raise a higher amount of capital to fund the clinical development of its assets than our forecasts currently assume. While our model accounts for financing(s) as long-term debt, the company may need to issue equity instead, at pricing that may not be favourable for current shareholders and could lead to significant dilution. We believe that identification of a partner will be key to ensuring the clinical success of IMX-110 and funding development through capital-intensive clinical trials. Any challenges in securing a partner could postpone product development and/or adversely affect the economics of a potential licensing transaction.

## Valuation

We value Immix Biopharma at US\$56.7m or US\$4.1 per share. Our valuation is based on a risk-adjusted NPV calculation for IMX-110 in STS (rNPV US\$26.9m or US\$1.9 per share) and solid tumour indications (rNPV US\$11.4m or US\$0.8 per share) and incorporates a net cash position of US\$18.4m at end-June 2022. In our valuation we apply a discount rate of 12.5% and assume a full licencing deal for IMX-110 is found in mid-2025, after results from the combination and monotherapy studies are reported in late-2024. A breakdown of our valuation assumptions can be found in Exhibit 9.

### Exhibit 9: Valuation assumption breakdown

Asset (indication)	Assumptions
IMX-110 (STS)	<ul style="list-style-type: none"> <li>■ <b>Target population:</b> we assume <b>13,190 patients</b> will be diagnosed with STS in the US in 2022 and the number will grow by 2% a year. In the EU, we assume an incidence rate of <b>0.005%</b>. Noting the unmet medical need in STS and accounting for Yondelis and Votrient losing patent protection in 2023, we assume a peak market penetration of 20%.</li> <li>■ <b>Pricing:</b> based on an estimated price per patient per year for Yondelis of US\$79k (EvaluatePharma), we assume a price for IMX-110 in STS of US\$80k per patient per year in the US, with a 50% discount in the EU5.</li> <li>■ <b>Trial timelines and R&amp;D costs:</b> US\$1.25m in FY22 followed by US\$2.5m in both FY23 and FY24 to complete the Phase IIa trial in STS. We assume full results from this trial will be available at end-FY24 and a full licensing deal for IMX-110 will be signed in 2025, with the licensee assuming all subsequent development and commercialisation costs.</li> </ul>
IMX-110 (solid tumours)	<ul style="list-style-type: none"> <li>■ <b>Target population:</b> we assume Immix will target a solid tumour indication with a large patient population where PD-(L)1 therapies are commonly used. We model our patient population using relevant statistics for non-small cell lung cancer (NSCLC). New cases of lung cancer in 2022 estimated to be <b>c 236k patients</b>, <b>84%</b> of which are NSCLC and <b>28%</b> of which are PD-1 high. Due to the large size and highly competitive nature of this market we assume a peak penetration of 5%</li> <li>■ <b>Pricing:</b> in line with our assumed pricing in STS, we assume a price for IMX-110 in solid tumours of US\$80k per patient per year in the US, with a 50% discount in the EU5</li> <li>■ <b>Trial timelines and R&amp;D costs:</b> US\$1.25m in FY22 followed by US\$2.5m in both FY23 and FY24 to complete the Phase Ib trial in solid tumours. We assume full results from this trial will be available at end-FY24 and a full licensing deal for IMX-110 will be signed in FY25, with the licensee assuming all subsequent development and commercialisation costs.</li> </ul>

Source: Edison Investment Research

Over 2022 and 2023, the two market leading treatments for STS (Yondelis and Votrient) will lose patent protection in the United States, which in our view, could create significant competition to IMX-110, if approved, from generic market entrants. In addition, the STS development pipeline is busy, with products like Adaptimmune's Afami-cel, Karyopharm's Xpovio and TRACON Pharmaceutical's envafolimab all estimated for potential approval in 2023 (as cited by EvaluatePharma). However, given the clear unmet medical need in STS, we assume a peak penetration for IMX-110 in STS of 20% in both the US and EU5. We assume IMX-110 is approved in STS by the FDA in early-2028, and estimate combined peak sales in the US and EU5 of US\$403.6m are reached in 2033. Our estimated price of US\$80,000 per patient per year is comparable to the 2021 per patient cost of Yondelis in 2021 (US\$70k, EvaluatePharma).

For the IMX-110 in solid tumours programme (Phase Ib to start in Q422), we have assumed the company will subsequently look to focus on one of the larger solid tumour indications (where unmet medical needs still exist) once this programme enters Phase II trials. Additionally, we have assumed an indication where PD-(L)1 therapies are commonly used and have therefore modelled our patient population using NSCLC as a proxy indication. We will revisit these assumptions as data from the trial is made available in throughout 2023 and 2024. A breakdown of our risk-adjusted NPV can be found in Exhibit 10.

Exhibit 10: Immix Biopharma rNPV breakdown							
Product	Launch	Peak	Peak sales (US\$m)	Value (US\$m)	Probability	rNPV (US\$m)	rNPV/ share (US\$)
IMX-110 (STS)	2028	2033	403.6	164.2	15%	26.9	1.9
IMX-110 (solid tumours)	2029	2035	484.9	142.1	10%	11.4	0.8
Net cash on 30 June 2022				18.4	100%	18.4	1.3
<b>Valuation</b>				<b>324.3</b>		<b>56.6</b>	<b>4.1</b>

Source: Edison Investment Research

According to our model, 47% of value is generated from IMX-110 in STS, 20% from IMX-110 in combination with tislelizumab in solid tumours and 33% from the company's cash position at 30 June 2022. Our valuation assumes a licensing deal is signed for IMX-110 in all indications in FY25, assuming positive results from the Phase IIb trial in STS and Phase Ib tislelizumab combination trial at end-2024. Considering the company's collaboration with BeiGene, we believe this is a reasonable assumption. Based on our assessment of past licensing deals for Phase I and II assets indicated for STS, we have assumed a total deal value of US\$210m, comprising a US\$30m upfront payment and US\$180m in sales, development and regulatory milestones. We also assume 15% royalties on net sales. Owing to the respective stages of development, we apply a probability of success of 15% to IMX-110 monotherapy in STS and 10% in solid tumour indications.

## Financials

As a pureplay biotechnology company focused on research and development, Immix Biopharma does not record any revenues. In FY21 the company reported an operating loss of US\$1.35m, consisting of US\$0.13m in R&D expenses and US\$1.23m in general and administrative expenses. The large increase in G&A costs from a year prior (FY20: US\$0.21m) was due to costs associated with the company's successful listing on the Nasdaq in [December 2021](#). The reported loss before tax in FY21 was US\$24.38m, which was substantially influenced by a reduction in the fair value of derivative liabilities held by the company of US\$22.76m. In total, the company reported a net cash outflow from operating activities of US\$1.59m in FY21 rising to US\$2.04m in H122. In H122, the company reported an increased operating loss of US\$2.89m (R&D: US\$1.28m, G&A: US\$1.65m) as the clinical development of IMX-110 ramped up over the period.

As we expect a ramp up of clinical activities from Q422, we estimate R&D expenses for FY22 to be US\$3.52m, with roughly US\$2.5m being allocated to the development of IMX-110 and c US\$1m for

additional R&D costs associated with preclinical activities. As we expect the Phase Ib (combination) and IIa (monotherapy) trials will be running simultaneously over the following years, we anticipate a substantial increase in R&D expenditure to US\$6.0m in FY23 with a roughly similar expense recorded in FY24. We base our R&D costs on estimated expenses incurred by the company in previous clinical trials and management's communicated budget of c US\$11m for both IMX-110 trials. We expect general and administrative expenses will grow to US\$2.70m in FY22, corresponding to the increased clinical preparations and commencement of trials, with a more modest growth of 2% in FY23 and beyond as the IMX-110 programme continues. Considering our estimated R&D and general and administrative costs, we estimate operating losses for Immix Biopharma in FY22 and FY23 of US\$6.22m and US\$8.77m respectively. This translates into a net cash outflow from operating activities of US\$5.41m in FY22 and US\$8.79m in FY23.

The company [floated](#) on the Nasdaq in December 2021, raising net proceeds of US\$18.65m (4.2m shares of common stock at US\$5.00 per share for US\$21m in gross proceeds), and an additional US\$2.91m in net proceeds in January 2022 from the exercise of the underwriter's over-allotment option in connection with the IPO (630k shares of common stock). Accordingly, the company had a cash position of US\$18.40m at end-H122 and no debt. Immix reported a cash burn rate of US\$2.04m over H122. Considering our forecast increase in operating expenses, we estimate the company's operations are funded to Q424. We expect top-line results from the Phase Ib combination trial and Phase IIa monotherapy trial for IMX-110 will be reported in Q424, and as such, the company will need to raise additional capital in FY2024 of c US\$10m, by our estimates. We anticipate this funding could support operations past top-line data readouts in Q424 until a licensing deal is found, which we estimate to be in mid-2025. If a licensing deal in line with our estimates can be realised, we believe this could bring the company to operating sustainability from mid-2025. We note that should clinical timelines be delayed, or the company begins new clinical development programmes, our cash requirement forecasts may need to be increased.

**Exhibit 11: Financial summary**

Accounts: IFRS; year-end 31 December; US\$000s	2019	2020	2021	2022e	2023e
<b>PROFIT &amp; LOSS</b>					
Total revenues	0	0	0	0	0
Cost of sales	0	0	0	0	0
Gross profit	0	0	0	0	0
Total operating expenses	(842)	(454)	(1,352)	(6,216)	(8,770)
Research and development expenses	(583)	(248)	(127)	(3,520)	(6,020)
SG&A	(259)	(206)	(1,225)	(2,696)	(2,750)
EBITDA (normalized)	(841)	(452)	(1,350)	(6,215)	(8,769)
Operating income (reported)	(842)	(454)	(1,352)	(6,216)	(8,770)
Finance income/(expense)	(110)	(102)	(180)	0	0
Exceptionals and adjustments	0	(574)	(22,846)	0	0
Profit before tax (reported)	(952)	(1,130)	(24,378)	(6,216)	(8,770)
Profit before tax (normalised)	(952)	(555)	(1,313)	(6,085)	(8,770)
Income tax expense (includes exceptionals)	(21)	(18)	(6)	(12)	(18)
Net income (reported)	(973)	(1,148)	(24,384)	(6,229)	(8,788)
Net income (normalised)	(973)	(572)	(1,319)	(6,098)	(8,788)
Basic average number of shares, m	1.1	3.4	3.7	13.8	13.9
Basic EPS (US\$)	(0.86)	(1.02)	(6.64)	(0.45)	(0.63)
Adjusted EPS (US\$)	(0.86)	(0.51)	(0.36)	(0.44)	(0.63)
Dividend per share	0.00	0.00	0.00	0.00	0.00
<b>BALANCE SHEET</b>					
Property, plant and equipment	10	7	6	4	3
Total non-current assets	10	7	6	4	3
Cash and equivalents	734	391	17,644	15,043	6,256
Current tax receivables	176	127	26	165	165
Trade and other receivables	0	0	0	0	0
Other current assets	24	14	516	516	516
Total current assets	933	532	18,186	15,724	6,937
Non-current loans and borrowings	0	0	0	0	0
Non-current lease liabilities	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Total non-current liabilities	0	0	0	0	0
Accounts payable	248	252	143	977	977
Illustrative debt	0	4,050	0	0	0
Current lease obligations	0	0	0	0	0
Other current liabilities	4,342	968	59	0	0
Total current liabilities	4,589	5,270	202	977	977
Equity attributable to company	(3,646)	(4,731)	17,990	14,750	5,963
<b>CASH FLOW STATEMENT</b>					
Net Income	(973)	(1,148)	(24,384)	(6,229)	(8,788)
Depreciation and amortisation	1	2	2	2	1
Share based payments	0	0	219	131	0
Other adjustments	0	575	22,964	0	0
Movements in working capital	182	166	(391)	686	0
Cash from operations (CFO)	(790)	(405)	(1,589)	(5,410)	(8,787)
Capex	(7)	0	(1)	0	0
Acquisitions & disposals net	0	0	0	0	0
Other investing activities	0	0	0	0	0
Cash used in investing activities (CFIA)	(7)	0	(1)	0	0
Capital changes	1,050	0	18,849	2,914	0
Debt Changes	0	0	0	0	0
Other financing activities	0	0	0	(106)	0
Cash from financing activities (CFF)	1,050	0	18,849	2,808	0
Cash and equivalents at beginning of period	462	734	391	17,644	15,043
Increase/(decrease) in cash and equivalents	253	(405)	17,259	(2,602)	(8,787)
Effect of FX on cash and equivalents	19	62	(5)	0	0
Cash and equivalents at end of period	734	391	17,644	15,043	6,256
Net (debt)/cash	734	(3,659)	17,644	15,043	6,256

Source: Immix Biopharma company accounts, Edison Investment Research

Contact details	Revenue by geography
11400 West Olympic Blvd Suite 200 Los Angeles, CA 90064 United States of America +1 (310) 651 8041 <a href="http://www.immixbio.com">www.immixbio.com</a>	N/A
Management team	
<b>Co-founder &amp; CEO: Dr Ilya Rachman</b> Dr Rachman is a physician, scientist and former community clinical faculty member at UCLA. He received both his MD and PhD from the University of Illinois, and his MBA from UCLA Anderson. Dr Rachman previously founded a clinical research organization that conducted clinical trials of pharmaceutical drugs and has completed several clinical trials as a principal investigator himself. His previous experience has helped establish strong relationships in the clinical research industry.	<b>CFO: Gabriel Morris</b> Mr Morris has been managing partner of Alwaysraise LLC, a life sciences advisory and investment firm based in San Francisco. Mr Morris was previously the interim chief financial officer of Zap Surgical Systems, a brain radiosurgery company. Mr Morris led cross-border mergers & acquisitions transactions during his time at Goldman Sachs and other global investment banks, where he worked for more than a decade and participated in over US\$50bn in completed transactions. He received his BA from the Columbia University in the City of New York.
<b>Chief medical officer &amp; head of clinical development: Dr Graham Ross</b> Dr Ross is an experienced pharmaceutical physician executive with a successful track record of development and post-marketing activities across a range of cancer therapeutics. Prior to joining Immix Biopharma, Dr Ross was senior medical science director at AstraZeneca and global clinical leader at Roche Pharmaceuticals. Prior to Roche, Dr Ross was director of clinical development at GlaxoSmithKline for a decade. Dr Ross trained in oncology in Durban, South Africa, and specialized a second time as a pharmaceutical physician in the UK.	
Principal shareholders	(%)
Hsu Jason	33.36%
MESA VERDE VEN PTNR III	7.37%
Torchilin Vladimir	6.51%
Rachman Ilya	6.49%
SENN SEAN	6.47%
Morris Gabriel	2.32%
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Frankfurt +49 (0)69 78 8076 960  
Schumannstrasse 34b  
60325 Frankfurt  
Germany

London +44 (0)20 3077 5700  
280 High Holborn  
London, WC1V 7EE  
United Kingdom

New York +1 646 653 7026  
1185 Avenue of the Americas  
3rd Floor, New York, NY 10036  
United States of America

Sydney +61 (0)2 8249 8342  
Level 4, Office 1205  
95 Pitt Street, Sydney  
NSW 2000, Australia