IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

FORTIS ADVISORS LLC, solely in its capacity as representative of former stockholders of Auris Health, Inc.,	)	
Plaintiff,	)	
v.	)	C.A. No. 2020-0881-LWW
JOHNSON & JOHNSON, ETHICON, INC., ALEX GORSKY, ASHLEY MCEVOY, PETER SHEN, and SUSAN MORANO,	)	
Defendants.	)	

MEMORANDUM OPINION

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WILL, Vice Chancellor

Earnout provisions are common risk allocation tools in merger agreements, particularly involving private company sellers. The buyer pays an upfront sum and an additional amount if the seller's business achieves specific targets by a deadline. This contingent approach lessens the buyer's risk of overpaying where the seller's future performance is uncertain. The seller, however, risks losing the earnout payment along with operational control after closing. A seller may be loath to agree to an earnout structure without contractual assurances from the buyer and a strong belief in the value of its business.

The seller in this case had both. Auris Health, Inc. was a venture-backed startup on a path to bring life-changing technologies to market. Led by Dr. Frederic Moll, the visionary architect of robotic surgery, Auris had developed two novel surgical robots in record time: Monarch and iPlatform. Monarch had unmatched capability to diagnose and treat lung cancer. And iPlatform took Moll's original market-leading surgical robot to new heights with innovative features for laparoscopic and endoscopic procedures.

While Auris was making strides, Johnson & Johnson was attempting to develop its own surgical robot called Verb. Entering the surgical robotics market was vital for J&J. Yet Verb was falling increasingly behind the schedule J&J had announced to the market, despite J&J's colossal investments. J&J looked to Auris as a solution.

Auris was well funded and had strong prospects. It was wary of an acquisition, especially by J&J since Verb was a potential competitor of iPlatform. J&J understood Auris's hesitations and put together a proposal it would not refuse.

J&J offered to pay $3.4 billion up front and another $2.35 billion upon the achievement of two commercial and eight regulatory milestones—five for iPlatform, two for Monarch, and one that could be satisfied by either robot. The regulatory milestones were ambitious, but corresponded to approvals for procedures that the Auris robots were on track to complete. Auris agreed to an earnout component after securing J&J's commitment to devote commercially reasonable efforts befitting a "priority medical device" in furtherance of the milestones.

J&J's promise to Auris was broken almost immediately after closing. Instead of providing efforts and resources to achieve the regulatory milestones, J&J thrust iPlatform into a head-to-head faceoff against Verb called "Project Manhattan." Verb and iPlatform were forced to complete a series of procedures to be ranked against one another. Auris feared that a poor performance would be the end of iPlatform since it had learned J&J's robotics budget left no room for Verb and iPlatform to be developed in parallel. J&J would either combine the robots or kill one.

The iPlatform alpha robot was months old. Verb was in its beta iteration after years of development. For iPlatform to survive a surgical showdown against the more advanced robot, the Auris team spent countless hours creating engineering and

software workarounds. Progress toward iPlatform's regulatory milestones ceased while technical debt from shortcuts in its development amassed.

Both robots successfully completed the assigned procedures. J&J decided that iPlatform was the better bet. But for iPlatform, winning Project Manhattan was losing. To salvage its years of investment in Verb, J&J directed that Verb's hardware and team be added to iPlatform. The iPlatform robot effectively became a parts shop for Verb.

J&J knew Project Manhattan would hinder, rather than promote, iPlatform's achievement of the regulatory milestones. It also knew that combining iPlatform and Verb would cause further complications. But J&J viewed the resulting delays as beneficial since it could avoid making the earnout payment. When J&J's actions put the first iPlatform milestone out of reach, the other milestones fell like dominos.

J&J wrote off the iPlatform milestones under the pretext of an unforeseen policy change that would require the robot to achieve regulatory clearance through a different pathway than the one listed in the merger agreement. J&J then implemented an employee incentive plan with different targets. Auris's former stockholders proceeded to sue for breach of contract, breach of the implied covenant of good faith and fair dealing, and fraud.

J&J's defenses to these claims take two main forms. First, J&J asserts that the merger agreement gave it broad discretion to use the Auris products in a way that

advanced J&J's overall robotics strategy without regard to the milestones. The merger agreement says otherwise. Second, J&J blames the missed milestones on iPlatform's technical problems. This defense is dubious; it was concocted after J&J was sued. The record indicates that the technical issues were both expected and solvable.

After weighing an abundance of evidence, I find that J&J breached its contractual obligations. The bespoke earnout provision negotiated by the parties required J&J to treat iPlatform as a priority device, to provide efforts in support of the regulatory milestones, and to avoid making decisions based on the contingent payment. J&J violated each obligation—most blatantly when iPlatform was made to compete against and combine with Verb. J&J also breached the implied covenant of good faith and fair dealing when it failed to devote efforts to achieve the revised regulatory pathway. But J&J did not breach the merger agreement in relation to the Monarch regulatory milestones.

Additionally, Auris claims that J&J fraudulently induced it to merge by promising vast resources and a "light touch" integration. For the most part, the challenged statements are fluffy, forward-looking, and aspirational. There is an exception. One Monarch milestone involved regulatory clearance by a near-term deadline using a J&J-developed catheter. J&J told Auris that this milestone was so certain to be met that J&J viewed the associated payment as up front consideration.

J&J neglected to mention that it was under a regulatory investigation because a patient in a clinical study using the catheter had recently died, which put the milestone in doubt.

Auris is entitled to damages for J&J's breaches of contract and of the implied covenant of good faith and fair dealing as they relate to the iPlatform regulatory milestones. It is also entitled to damages for fraud concerning the Monarch milestone. Damages with interest exceed $1 billion, which compensates Auris's former stockholders for the earnout payment they would have received absent J&J's failed efforts and fraud. What remains irretrievably lost is the transformative potential of Auris's robots.

I. BACKGROUND

The following facts were stipulated to by the parties or proven by a preponderance of the evidence at trial.[1] The record supporting these findings of fact includes the testimony of 23 fact and 9 expert witnesses over 10 trial days, 78 deposition transcripts, and 6,209 joint exhibits.[2]

A. Dr. Moll and the da Vinci Robot

Robotically assisted surgery allows physicians to perform minimally invasive operations with computer-assisted equipment.[3] Surgical robots, or Robotically Assisted Surgical Devices (RASDs), are used to perform these procedures. RASDs typically comprise several components and subsystems, including a surgeon console, a computing tower, and a surgical bed or cart with mounted robotic arms attached to instruments.[4]

Dr. Frederic Moll first witnessed early progress in robotic surgery as part of a Stanford Research Institute (SRI) project funded by the United States Department of

[1] Joint Pre-trial Stipulation and Order (Dkt. 523) ("PTO").

[2] Facts drawn from exhibits jointly submitted by the parties are referred to by the numbers provided on the parties' joint exhibit list and cited as "JX –" unless otherwise defined. *See* Dkt. 575. Pin cites for joint exhibits refer to the page of the exhibit as marked rather than internal or Bates pagination, unless otherwise noted. Deposition transcripts are cited as "[Name] Dep." *See* Dkt. 509. Trial testimony is cited as "[Name] Tr." *See* Dkts. 545-54.

[3] PTO ¶ 75.

[4] *Id.* ¶ 76.

Defense several decades ago.[5] SRI's objective was to create a means for surgeons to operate remotely on patients in the battlefield.[6] Though rudimentary, the device SRI developed could transmit a surgeon's hand movements from a computer to actuators in the field that controlled a robotic instrument.[7]

Moll saw the "potentially transformative" promise of robotic-assisted surgery as having "enormous implications in laparoscopy."[8] Laparoscopy is a minimally invasive surgical technique in which narrow tubes are inserted into the abdomen or pelvis through puncture wounds.[9] Moll had been exposed to emerging laparoscopy techniques during his medical residency and turned his focus to developing safe laparoscopic tools and methods.[10] He observed that a trade-off to minimal openings in the body is the difficulty surgeons face in reaching the relevant anatomy.[11] Using the insights gained at SRI, Moll imagined that computer replication of hand movements outside the body to robotic hands inside the body could resolve laparoscopic access barriers.[12]

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[5] Moll. Tr. 9-10.

[6] *Id.*

[7] *Id.* at 10.

[8] *Id.*

[9] *Id.* at 6-7.

[10] *Id.* at 6.

[11] *Id.* at 10.

[12] *Id.*

In 1995, Moll founded Intuitive Surgical, Inc. to pursue the objective of making laparoscopic surgery intuitive.[13] He developed a product called the da Vinci robot—a cart-based system with two arms to hold surgical instruments and a third arm for a viewing laparoscope.[14] Moll's vision was to "mimic the capabilities of open surgery inside the body" by using a computer interface to transmit movements to tiny tools inside the abdomen in a "systematic and controlled way."[15]

Developing the da Vinci robot was no small feat. The Intuitive team encountered many technical challenges, including problems with tool function, software stability, arm collisions, and intra-device heat distribution.[16] The issues were addressed with mitigation strategies now typical to robotic surgery.[17] Dr. Barry Gardiner, a physician who pioneered laparoscopy in general surgery, contributed vital clinical knowledge to solve these issues and develop the robot.[18]

The da Vinci system was not Moll's only innovation at Intuitive. He also instituted the minimally viable product (MVP) approach, which has become the

[13] PTO ¶ 77; Moll Tr. 11-12.

[14] Moll Tr. 11-12.

[15] *Id.* at 13.

[16] *Id.* at 16-17.

[17] *Id.* at 17-19 (discussing the use of surgical assistants to move and adjust the robot during a procedure, which remains standard today).

[18] Moll Tr. 14; *see* JX 2598 at 3.

industry standard for bringing new, complex medical devices to market.[19] The MVP development strategy involves creating a functional prototype to gain feedback from an engineering and clinical standpoint before adding more complex features.[20] This method increases efficiency by allowing for testing of a lower-risk device before making further investments.[21] Regulatory approval is sought for the stripped-down version, ensuring that it meets patient safety and effectiveness requirements.[22]

Intuitive followed an MVP strategy with the da Vinci system. It first sought regulatory approval for a basic three-arm version of the device.[23] In 2000, the Food and Drug Administration (FDA), which regulates the sale of medical devices in the United States and monitors their safety and effectiveness, approved the minimally viable da Vinci robot through the 510(k) process.[24]

The 510(k) (or Premarket Notification) process is one of three regulatory pathways through which high or moderate risk medical devices obtain FDA approval.[25] The 510(k) pathway is for low to moderate risk devices with a legally

[19] Moll Tr. 15-17; *see* Gompers Tr. 1935-36; Grennan Dep. 71-72; Shen Tr. 1169.

[20] Moll Tr. 15-16.

[21] *Id.* at 16; *see* Khan Tr. 3041-3042.

[22] Moll Tr. 16.

[23] JX 14; *see* Moll Tr. 15-16.

[24] Moll Tr. 19; PTO ¶ 79.

[25] PTO ¶ 81.

marketed predicate device.[26] It involves a comprehensive review of appropriate safety and performance data to determine if a new device is substantially equivalent to an approved predicate.[27] The second pathway is a De Novo Classification Request, which is used when a novel low to moderate risk device lacks a legally marketed predicate.[28] De Novo approval often requires clinical testing data to demonstrate a device's safety and effectiveness.[29] The third pathway, called Premarket Approval (PMA), is the most onerous and required for high risk devices.[30]

Consistent with its MVP strategy, Intuitive went on to pursue and receive 510(k) clearance for a four-arm version of the robot in 2002.[31] The da Vinci robot was rapidly adopted by customers and Intuitive became focused on manufacturing and selling the system. Moll, having achieved his objective, moved on to "continue down a path of innovation."[32]

Today, Intuitive is considered the market leader in RASDs.[33] It has a market capitalization of over $100 billion and controls a majority of the surgical robotics

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[26] *Id.*

[27] *Id.* ¶ 82; *see* JX 4492 ("Wittwer Rep.") ¶ 137.

[28] PTO ¶ 81.

[29] Wittwer Rep. ¶ 137.

[30] PTO ¶ 81; *see* Wittwer Rep. ¶ 148.

[31] *See* JX 4511 ("Tillman Rep.") ¶ 94.

[32] Moll Tr. 21.

[33] PTO ¶ 77.

market.[34] Intuitive's robots have performed hundreds of thousands of procedures worldwide, cementing Moll's legacy as the "father of robotic surgery."[35]

B. Auris and the Next Generation of Surgical Robots

Moll set out to start a new RASD innovation company called Auris Health, Inc. In 2009, Moll raised Auris's seed funding.[36] Early investors included venture capital funds such as J&J Innovation, a subsidiary of Johnson & Johnson.[37]

Moll intended that Auris would advance RASDs beyond the base architecture of da Vinci to match strides in minimally invasive surgery—specifically in endoscopy.[38] Endoscopy involves inserting a flexible tube called an endoscope into the body through its natural openings.[39] He hoped to improve endoscopic technique with robotics as he had done for laparoscopy.[40]

Early-stage Auris was a "vision-oriented, mission-oriented" company.[41] Its visionary leaders included not only Moll but also Gardiner, who remained

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[34] Moll Tr. 21; *see* JX 711 at 19-22; Royan Tr. 1376-77.

[35] JX 1868; *see* Moll Tr. 21; JX 1868; Shen Tr. 1106; Grennan Tr. 2555.

[36] PTO ¶ 87.

[37] *Id.* ¶ 88.

[38] Moll Tr. 22-23.

[39] *Id.* at 23.

[40] *Id.* at 23-24.

[41] DeFonzo Tr. 316, 319.

instrumental in providing clinical expertise.[42] A combination of leadership and dynamism gave Auris the momentum to rapidly develop its first RASD, called ARES, and secure FDA clearance.

1. ARES

Auris began developing the ARES robot in 2012.[43] It was designed for endoscopic procedures.[44] David Mintz, an engineer who had worked alongside Moll since Intuitive's early days, was tapped to spearhead the project.[45]

After 18 months of development, Auris began using ARES in overseas clinical studies for endourology (or urology) and bronchoscopy.[46] Endourology involves the use of endoscopic surgical techniques to treat conditions affecting the urinary tract.[47] Bronchoscopy is a procedure in which a flexible tube called a bronchoscope is passed through a patient's throat to view or treat the lungs and airways.[48]

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[42] Moll Tr. 27.

[43] Mintz Tr. 554-55.

[44] *Id.*

[45] Moll Tr. 24-25.

[46] Mintz Tr. 555.

[47] *See* Moll Tr. 64; *see also* PTO ¶ 154.

[48] *See* Moll Tr. 33; *see also* PTO ¶ 147.

ARES received 510(k) clearance for bronchoscopy in May 2016, using Intuitive's da Vinci robot as its predicate device.[49] It was never commercialized. ARES was, instead, a step in Auris's MVP strategy. Auris assessed ARES's clinical capabilities first before building commercial RASDs with the benefit of that knowledge.[50]

2. Monarch

Auris's Monarch robot was the "commercial embodiment" of ARES.[51] In 2016, Moll hired Richard Leparmentier, an experienced engineering manager, to lead the Monarch project.[52]

Monarch is a revolutionary RASD. It can send a flexible endoscope through lung airways to locate, identify, and biopsy lesions found on preoperative computed tomography (CT) scans.[53] Its initial iteration, called Monarch Bronch 1.0, could navigate the outer lung non-invasively. In March 2018, it became the first in the Monarch device line to receive 510(k) clearance.[54] The next iteration of Monarch—

[49] JX 275.

[50] Moll Tr. 25.

[51] *Id.* at 26.

[52] *Id.* at 32-33.

[53] JX 5054; Moll Tr. 33.

[54] PTO ¶ 91; JX 334; JX 331; *see* Leparmentier Tr. 979.

an endourology-focused device called Monarch Uro—received pre-submission feedback from the FDA in November 2018.[55]

3. iPlatform

In 2016, Auris began to create another robot in parallel with Monarch: the iPlatform surgical system. Mintz was put in charge of the iPlatform project.[56] Josh DeFonzo was hired as Auris's head of operations to oversee both the iPlatform and Monarch programs.[57]

iPlatform was devised as a bed based RASD with integrated surgical arms, a physician console, and a control tower.[58] It would be differentiated from da Vinci in several ways. Unlike the cart-based da Vinci system, which could only fit in large or custom-built operating rooms, iPlatform had "zero footprint" since its robotic arms were mounted beneath a surgical bed.[59] Though iPlatform would first be developed for laparoscopic applications (like da Vinci), it would eventually gain concomitant (laparoscopic and endoscopic) capabilities.[60] iPlatform had six robotic arms versus da Vinci's four.[61]

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[55] JX 858; *see* JX 637.

[56] Moll Tr. 26.

[57] *Id.* at 27.

[58] PTO ¶ 99; Moll Tr. 26-31; JX 5064.

[59] Mintz Tr. 566.

[60] Mintz Tr. 567; Moll Tr. 32; *see* JX 1347 at 5.

[61] Mintz Tr. 567; *see* JX 1347 at 5.

Within a year, the iPlatform prototype was completing labs on human cadavers using three robotic arms.[62] Cadaver labs are considered the ideal, ethical way to test a RASD's safety and effectiveness before live experimentation.[63] By summer 2017, iPlatform was completing cadaver lab procedures using five robotic arms.[64]

In December 2017, iPlatform reached "concept freeze"—a "critical step" where a design concept is deemed viable.[65] The design included iPlatform's bed-based architecture, six so-called "Silverton" robotic arms, insertion tools, and more.[66] Mintz presented its risk case and solutions to Auris's executive team for approval.[67] The conceptual design was approved, and iPlatform proceeded to the next stage of product development.

Auris began to work iteratively with the FDA on a plan for regulatory approval for iPlatform. In August 2018, Auris made its first 510(k) pre-submission to the FDA, listing a cart-based da Vinci RASD as the predicate device.[68] Auris's pre-submission form discussed a bronchoscopy indication for iPlatform.

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[62] JX 292 at 7; Gardiner Tr. 743-47; *see also* JX 5012 at 1.

[63] Gardiner Tr. 745.

[64] JX 292 at 7; *see* JX 1347.

[65] Mintz Tr. 557-59; JX 1347.

[66] JX 292 at 5-6, 30, 35-37, 57, 84.

[67] Mintz Tr. 560-6; JX 292 at 20, 141.

[68] JX 545 at 34.

In October 2018, the FDA provided feedback to Auris, including that it would require clinical testing and data to be presented with iPlatform's application.[69] The FDA also explained that the listed indication was a mismatch for the predicate device.[70] Because the cited predicate device lacked a bronchoscope and did not perform the bronchoscopic procedures iPlatform's application contemplated, the FDA said that it was "unclear if the 510(k) pathway [wa]s appropriate."[71] In response, Auris withdrew bronchoscopy from iPlatform's 510(k) application and changed the predicate device to a more apt da Vinci robot.[72] Auris believed that if it addressed the FDA's feedback and provided appropriate clinical data, iPlatform would receive 510(k) clearance.[73]

Auris continued to refine its iPlatform prototype. Prostatectomy and Nissen fundoplication cadaver procedures were successfully completed in the fall of 2018.[74]

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[69] JX 743 at 5.

[70] *Id.* at 4.

[71] *Id.* at 3.

[72] JX 2468 at 5; Mintz Tr. 604-06.

[73] JX 743 at 3; Mintz Tr. 605-06; *see also* JX 2468.

[74] JX 699; Gardiner Tr. 748-49. A prostatectomy is a procedure to remove all or part of the prostate. A Nissen fundoplication is an upper abdominal procedure that treats gastroesophageal reflux disease. *See Prostatectomy*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/prostatectomy/ about/pac-20385198 (last visited Aug. 31, 2024); *Nissen Fundoplication*, Cleveland Clinic, https://my.clevelandclinic.org/health/treatments/ 4200-nissen-fundoplication (last visited Aug. 31, 2024); *see also* Gardiner Tr. 728-30; Mintz Tr. 580.

By December 2018, the "alpha" version of iPlatform had been built, roughly a year after the concept freeze stage.[75]

C. J&J's Verb Robot

As robotic surgery gained momentum, Johnson & Johnson desired RASD market share. A significant portion of J&J's revenue came from its subsidiary Ethicon, Inc.'s sales of surgical instruments.[76] J&J recognized an "existential threat" to its instrument business as Intuitive-branded instruments were sold for the growing number of da Vinci robots in hospitals.[77]

In 2012, with new Chief Executive Officer Alex Gorsky at the helm, J&J partnered with SRI to develop a RASD to compete with da Vinci.[78] Pablo Garcia Kilroy was the lead engineer on the project.[79] When the RASD showed commercial potential in 2015, J&J formed a joint venture called Verb Surgical Inc. with Verily Life Sciences LLC (a subsidiary of Alphabet Inc.).[80] Kilroy became Verb's lead engineer.[81]

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[75] Mintz Tr. 569-70; PTO ¶ 99.

[76] JX 1529 at 7 (2018 tax form showing the largest portion of J&J's revenues was from surgical and medical instruments sales, totaling over $4.149 billion). This decision refers to Ethicon and Johnson & Johnson as "J&J."

[77] JX 215 at 4; Morano Tr. 1435; *see also* JX 5019 at 23.

[78] Kilroy Tr. 2139; Shen Dep. 10-12; JX 2661 at 6.

[79] Kilroy Tr. 2078.

[80] PTO ¶ 72; Kilroy Tr. 2078.

[81] Kilroy Tr. 2079.

Verb's robotic surgery system had three main structures: a table-mounted center component with four robotic arms, a user console for the surgeon to operate the robot, and a tower containing the controller for the robot and a vision system.[82] The user input devices for controlling the Verb robot were novel. Instead of using physical controls, magnetics tracked the surgeon's hand movements in an open console and reproduced them to guide the robot.[83]

Like iPlatform, Verb encountered challenges during the design process. They included dexterity issues both inside the body (like suturing and tying knots) and outside the body (involving arm collisions and maneuverability).[84] Dexterity came with a trade-off in stiffness, which allowed for control of flexible apparatuses and surgical tools.[85] Verb also faced user interface issues, impairing the surgeon's ability to complete a procedure with ease in the open console.[86]

But unlike iPlatform, Verb was plagued by delays. By fall 2017, Gorsky learned that Verb had fallen significantly behind schedule.[87] J&J nonetheless aimed

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[82] *Id.* at 2082.

[83] *Id.* at 2084.

[84] *Id.* at 2085, 2087-88; *see also* JX 912 at 13-18; Kilroy Dep. 62:4-17.

[85] Kilroy Tr. 2084-85

[86] *Id.* at 2087.

[87] *See* JX 224 at 21 (J&J Sept. 28, 2017 Digital Surgery Update to Gorsky: "Verb launch is delayed, increasing hurdles to achieving the plan . . ."); *id.* at 33 ("Verb is our largest bet to establish a leading robotics presence. However, we do not believe it is currently on a path to deliver this."); *id.* at 41 (reflecting that since Q1 2015 to the present (3Q 2017),

for a 2020 commercial release. During an earnings call in January 2018, Gorsky said that Verb was "on track" for a 2020 launch date.[88]

The next month, Gorsky asked J&J's Board of Directors for an additional $400 million of funding for Verb to advance a "Gen 1 system towards launch in 2020."[89] While preparing for the meeting, Gorsky recognized the "significant importance of the project" and questioned whether J&J had the "right capabilities" to deliver the robot.[90] Susan Morano, J&J's Vice President of Business Development for the Medical Devices group who reported to Gorsky, conveyed to her colleagues that Gorsky had asked her "[h]ow did we get this so wrong (internally and with Verb)[?]"[91]

In June 2018, Ashley McEvoy became J&J's Executive Vice President, Worldwide Chairman of MedTech (f/k/a Medical Devices).[92] She reported directly to Gorsky during his tenure.[93] As the head of MedTech, McEvoy appreciated the

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Verb had fallen two years behind schedule for a U.S. launch date and required pre-launch funding of $430 million versus the anticipated $200 million).

[88] JX 290 at 18 (Gorsky: "I got a chance to visit see the prototype. I would say overall that it[']s on track and we're continuing to make refinements in it . . . So overall the project remains on track with our timelines and we're excited about it.").

[89] JX 647 at 2, 17.

[90] JX 295 at 2-3.

[91] *Id.* at 2.

[92] McEvoy Tr. 2565.

[93] *Id.*

need for J&J to disrupt the RASD market before more competitors could enter the space.[94] Gorsky told McEvoy to "take lead" on the Verb initiative and tackle risks to the project's announced 2020 launch date.[95]

Two months later, in August 2018, McEvoy sent Peter Shen to visit Verb for a "deep dive."[96] Shen, a mechanical engineer by training with limited robotics experience, was J&J's Global Head of MedTech Research & Development.[97] After his visit, Shen told McEvoy that despite some progress, the Verb team had yet to "declare [a] design concept" and suffered from "[c]hurning and lack of focus."[98] J&J's internal consulting group, Accelerando, was then asked to assess Verb's status. Its conclusions resulted in a revised launch date of 2022, which was given an 85% probability of success.[99] In October 2018, J&J set a reduced scope for the Verb RASD with a planned initial release outside the United States.[100]

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[94] *Id.* at 2567.

[95] JX 504; JX 711.

[96] JX 533; *see* McEvoy Tr. 2573.

[97] Shen Tr. 1102.

[98] JX 533.

[99] JX 711 at 3 ("Accelerando process was initiated resulting in revised delivery timelines of 2022 (vs. 2020)."); *id.* at 9 ("85% confidence date: Q4 2022").

[100] *Id.*

D. J&J's Interest in Auris

While Verb's setbacks compounded, J&J began to consider other ways to enter the RASD market. In early 2017, it evaluated investing in Auris, which J&J personnel had been aware of and impressed by since 2015.[101] Morano visited Auris and described it as a "key hedge" for J&J.[102]

In May 2017, J&J invested $45 million in Auris's Series D round and secured a board observer seat.[103] The investment followed extensive due diligence by J&J into the Monarch platform, including technical assessments by third-party product development consultant Sagentia Innovation.[104] By late 2017, J&J (including Morano) had learned about iPlatform and worried it could "take the wind out of Verb."[105]

In May 2018, J&J's Chief Scientific Officer William Hait, who led the company's Lung Cancer Initiative, visited Auris. After seeing Monarch's potential to diagnose and treat cancer in otherwise inaccessible areas of the lung, he became

[101] JX 142; JX 186; Morano Tr. 1438-40.

[102] Morano Tr. 1438-40; JX 186 at 3-4.

[103] JX 195; PTO ¶ 107.

[104] JX 475; Kozak Tr. 1579.

[105] JX 261 ("Big learning is that [Auris has] been quietly developing a mainframe [with] the potential to really disrupt as it combines their arms with their endoluminal . . . And they say it will launch in 2 years which if true will completely take the wind out of Verb.").

"maniacally focused" on gaining access to the robot.[106] Hait returned to J&J and gave a presentation to its executive committee on Monarch's unique potential to advance the Lung Cancer Initiative.[107] Gorsky asked Hait to be a point of contact for a J&J team exploring a deeper relationship with Auris.[108] Sagentia was charged with conducting additional technical due diligence into Auris's technology.[109]

In July 2018, Morano recommended to Gorsky that J&J invest another $200 million in Auris (called "Antwerp" internally at J&J).[110] Although the initial focus was on accessing Monarch given Hait's enthusiasm, iPlatform became a crucial factor. Shen expressed to Morano that he was "very concerned" Verb was "significantly behind" and suggested "explor[ing]" "iPlatform as a backup plan" for Verb.[111] At the same time, Gorsky told Morano that he "want[ed] [A]ntwerp added to [V]erb" with the "back end tech" shared.[112] To address this directive, Morano and her team prepared a presentation for Gorsky that outlined Auris's "'hybrid'

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[106] Hait Tr. 921-23; *see* Hait Dep. 266-68.

[107] Hait Tr. 922-23; *see* JX 95.

[108] JX 95.

[109] JX 447; JX 487; Kozak Tr. 1580-82.

[110] JX 495 at 9.

[111] JX 481.

[112] JX 485 (Morano reporting her conversation with Gorsky to McEvoy: "He wants antwerp added to verb – which I told I don't think makes sense but that it could absolutely be a separate endoluminal system . . . which he was ok with but wants the 'back end tech' shared – which I believe is our strategy.").

laparoscopic/[e]ndoluminal opportunity," including a "potential partnership with Verb."[113]

At Gorsky's request, Hait and Shen began collaborating on a plan to "mesh" Verb and iPlatform.[114] Gorsky felt the need to be "fully engaged" beyond his typical involvement with an investment because of Auris's importance to J&J's "future surgical and digital/robotics platform."[115]

E. J&J's Acquisition Strategy

By August 2018, J&J hoped to obtain a controlling interest in or outright acquire Auris. McEvoy approved an acquisition assessment but asked that it be "done VERY quietly" since "Verb [was] in a fragile state."[116] Due diligence continued.[117] J&J's engineers visited the Auris site, spending hours asking Mintz

[113] JX 495 at 10.

[114] JX 507 (Hait to Shen: "I am now more fully aware of Antwerp in the context of your broader robotic/digital surgery initiative and would be happy to work closely with you to plan a strategy where we can mesh the two."); *see* Hait Tr. 941; *see also* JX 598 (Hait to McEvoy: "I reviewed VERB with the Med Device team and was impressed with the passion and progress but also heard significant challenges. Auris will likely be best in-class endoluminal robotic surgery and have a competitive laparoscopic instrument whereas VERB is likely to have the most sophisticated data analytics. Alex has challenged us to find a way to 'mesh' the two projects.").

[115] JX 506.

[116] JX 527 at 1.

[117] *See* JX 557.

"good, hard, technical questions, challeng[ing] [Auris] on the right points," and examining the robot.[118] Sagentia participated in J&J's technical diligence.[119]

Given the sensitivities with Verb, J&J proceeded cautiously. In September, Hait wrote to Shen: "[W]hat if we combine the engineering expertise of Auris and the iPlatform laparoscopic and endoluminal device with the data analytics of VERB[?] In this way, we will have hedged out bets in robotics, take[n] the lead in endoluminal, and protect[ed] at least some of our investment in VERB."[120] Shen responded that "there [were] major complexit[ies] and implications to this discussion" and asked to keep "the conversation within a small group for now."[121] Shen asked to talk when the two were together in Shanghai later that month.[122]

In the interim, J&J learned that Medtronic—a competitor—was interested in acquiring Auris.[123] The news prompted "a critical moment that require[d] [J&J] to accelerate."[124] Auris falling into a competitor's hands was a "doomsday scenario" for J&J.[125] In considering next steps, Shen told Morano that "iPlatform c[ould] be a

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[118] Mintz Tr. 575-77.

[119] JX 557 at 3.

[120] JX 600.

[121] *Id.*

[122] *Id.*

[123] JX 619.

[124] *Id.*

[125] JX 670 (Hait to Shen); *see also* JX 679.

plan B for [J&J]" but questioned whether J&J could "do both (Verb and iPlatform)."[126]

In late September, Shen and Hait met in Shanghai and discussed plans for Auris.[127] Shen later recapped the meeting for McEvoy, highlighting a "complementary" approach where Verb would focus on general surgery and iPlatform would have "combo capabilities" including endoluminal surgery.[128] He believed this was a "'Fail Safe plan for [J&J's] robotic strategy."[129] With the "go" from McEvoy, Shen and Hait presented their plan to Gorsky, who was "pleased."[130]

F. J&J's Acquisition Strategy

Hait was tasked with initiating acquisition discussions with Moll.[131] In his first outreach on October 1, 2018, Hait praised Monarch's unmatched capability to screen for lung cancer. He also shared that "[J&J's] medical device group ha[d] become increasingly impressed with iPlatform, as [the Auris] team makes

[126] JX 619.

[127] JX 664.

[128] JX 660.

[129] *Id.*

[130] *Id.*; JX 664.

[131] JX 661 at 2.

extraordinary progress."[132] Hait told Moll that J&J was interested "in exploring a more substantial relationship."[133]

Auris was, at the time, considering a new investment round to support the independent development of its robots. It was not searching for a buyer.[134] Auris's leadership felt that a merger, particularly with a large company, could cause a loss of the autonomy that had made its success possible.[135] With J&J in particular, Auris feared that Verb could displace iPlatform.[136]

J&J understood these concerns and strategized on finding "what matter[ed] most" to Auris.[137] Given the "criticality" of this issue, McEvoy and Gorsky "le[d] from the top" on strategy.[138] They—with Shen, Hait, Morano, and other senior leadership—prepared for an in-person meeting at Auris's Redwood City, California headquarters by assessing Auris's "[v]ision and [i]nterests."[139] These interests included Auris's desire to understand J&J's "vision [on] how Antwerp and Verb

[132] JX 661 at 2.

[133] *Id.* at 2.

[134] *See* Hebert Tr. 1398-99; Salehizadeh Tr. 1345.

[135] Moll Tr. 38-40.

[136] *Id.* at 40.

[137] JX 736 at 1.

[138] *Id.*

[139] JX 838 at 4.

coexist."[140] Gorsky's talking points for the Redwood City meeting said: "We see the Verb and Antwerp programs as complementary."[141] Gorsky represented as much to Moll during dinner in California, emphasizing that Verb and iPlatform would be developed in parallel and that iPlatform was a priority for J&J.[142]

On November 28, Gorsky called Moll to propose acquiring a 51% equity stake in Auris.[143] Auris had no interest in selling a majority of its business.[144] By mid-December, J&J began preparing a full acquisition proposal, including an earnout component based on regulatory and sales milestones.[145]

On January 2, 2019, Gorsky presented Moll with an offer to acquire Auris for a $3 billion upfront payment and $2 billion in potential earnout payments.[146] Gorsky represented that J&J would "spend multiples" of what Auris alone could invest in developing its robots.[147] Further diligence and negotiations ensued, with Auris

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[140] *Id.*

[141] *Id.* at 7.

[142] Moll Tr. 42; *see also* JX 838 (prepared talking points for Auris meeting); Morano Tr. 1517; DeFonzo Tr. 326-331.

[143] Gorsky Dep. 210-13; Morano Tr. 1458; JX 852; JX 837 at 28; JX 5100 at 4.

[144] *See* JX 929; Huffines Dep. 426-27.

[145] JX 934.

[146] PTO ¶ 110.

[147] JX 1004 at 6; Moll Tr. 45.

continuing to question whether J&J would expect iPlatform to compete with Verb, and J&J assuring Auris that it planned to fund and launch both products.[148]

G. The Ashley Challenge

Meanwhile, J&J was exploring a budget for its entire robotics division. McEvoy decided that the total robotics budget including "[V]erb, instruments, IT, [and] Antwerp" would be capped at "$500-$600" million per year.[149] This budget cap would later be called the "Ashley Management Decision" or "Ashley Challenge."[150] At J&J, a "management decision" is a top-down "budget challenge" for a division.[151]

On January 10, 2019, McEvoy's team sent her an estimated profit and loss statement for the robotics program.[152] The total expenses for Verb, Auris, and "Orthopedics" for 2019 through 2022 were projected to be $3.167 billion.[153] Hours later, a revised draft was circulated reflecting McEvoy's feedback.[154] A line item called "AAM RISK ADJUSTMENT" was added, which reduced total projected

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[148] JX 1028; JX 1032; *see* DeFonzo Tr. 480; Morano Dep. 218.

[149] JX 846.

[150] *Id.*; *see* JX 1090; McEvoy Tr. 2603-06.

[151] *See* Lenard Tr. 1787; Shen Tr. 1247.

[152] JX 1118 at 5.

[153] McEvoy Tr. 2610-15.

[154] JX 1119 at 1.

expenses for 2019 through 2022 to $2.296 billion.[155] McEvoy explained that the "AAM risk adjusted line-item" was "in reference to a proposed synergy between Verb/[iP]latform."[156] She felt these "synergies" were "potentially achiev[able]" once J&J brought "both platform teams together," after J&J had "more time to understand the synergy opportunities."[157]

H. Negotiations Progress.

J&J continued to conduct diligence throughout January. It learned about trade-offs in iPlatform's design and other system issues that the Auris team was working to resolve.[158] Both parties agreed to a three-stage diligence process and to defer further technical due diligence.[159]

Negotiations on deal terms progressed. On January 18, Auris sent J&J a counteroffer for $3.9 billion in upfront consideration and $3.5 billion in contingent payments based on regulatory and sales milestones for iPlatform and Monarch.[160] The regulatory milestones would be tied to 510(k) approval, which was the expected

[155] *Id.* at 6.

[156] JX 1139 at 1; *see* McEvoy Tr. 2607-16.

[157] JX 1135 at 1.

[158] JX 1141; JX 1145; JX 1284.

[159] Morano Tr. 1477; JX 1077; JX 1052.

[160] JX 1210.

pathway.[161] J&J offered that net sales milestones include sales of not only iPlatform and Monarch but also Verb "to address [Auris's] concerns about Verb."[162]

On January 24, Gorsky called Moll to deliver J&J's formal counteroffer. It included upfront cash consideration of $3.4 billion and a total potential earnout of $2.2 billion.[163] J&J spread the contingent payments across six milestones—four regulatory and two sales based.[164] One of the proposed milestones provided Auris with $100 million upon Monarch receiving FDA 510(k) approval for lung tissue ablation. Gorsky told Moll that this milestone was so "high[ly] certain[]" of being achieved that J&J viewed it as "effective 'up front'" consideration.[165]

I. The NeuWave Patient Death

The Monarch lung tissue ablation milestone required the use of an Ethicon device called the NeuWave FLEX Microwave Ablation System. The NeuWave FLEX is a catheter-based instrument that delivers microwave energy to ablate or destroy tissue.[166] At the time of J&J's January 24 offer, FLEX had regulatory approval for soft tissue ablation but not a lung-specific use.[167] Monarch, by contrast,

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[161] JX 1072 at 4; DeFonzo Tr. 363-64; Moll Tr. 58-59.

[162] JX 1072; JX 1027; JX 1077; JX 1145.

[163] JX 1215 at 5.

[164] *Id.*

[165] *Id.* at 6; *see also* JX 1249 at 3; Moll Tr. 51.

[166] Moll Tr. 50.

[167] JX 161 at 3.

had already attained FDA clearance for bronchoscopy and was approved only for lung procedures.[168]

In June 2018, NeuWave Medical (a subsidiary of J&J's Ethicon subsidiary) initiated a ten-patient study using FLEX to treat lung lesions.[169] On December 4, 2018, a study participant died weeks after being treated with FLEX.[170] J&J immediately reassigned leadership of the study to Hait, who suspected that the FDA would place the study on hold for some period.[171]

Hait was right. Nine days after the patient death was reported to the FDA, the FDA launched a for-cause inspection into whether the study violated FDA rules because NeuWave had not obtained an investigation device exemption (IDE) in advance.[172] An IDE provides FDA approval to perform a clinical trial of a device that has not been cleared for marketing or the intended indication.[173] The FDA investigation involved an in-person investigation at Ethicon's "sponsor site from December 13, 2018 to December 19, 2018."[174]

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[168] *See supra* note 54 and accompanying text.

[169] JX 1901 at 25; *see* JX 4511 at 88.

[170] JX 1901 at 30.

[171] Hait Tr. 961-63.

[172] JX 1673; JX 1550 at 157; *see* JX 2648 at 35, 36; JX 2313 at 8-9, 13.

[173] Wittwer Rep. ¶ 87.

[174] JX 1673 at 2; *see also* Wittwer Tr. 1964-65.

On January 14, 2019, J&J's Auris deal team was briefed on the NeuWave patient death.[175] They sought to understand whether the "patient death was going to affect the overall value of Auris."[176] Team members preparing talking points for Gorsky to deliver to Moll were mindful of the "nuances" to the Monarch lung tissue ablation milestone "and what will be required for the FDA approval (still in discussion)."[177] As of January 22, J&J's team believed that a to-be-offered year-end 2022 target for the Monarch lung tissue ablation milestone remained "achievable."[178]

On March 20, the FDA sent J&J a letter stating that it had concluded the use of FLEX on lung lesions posed a "significant risk" to participants and that J&J should have applied for an IDE before launching the study.[179] J&J received the FDA's letter on April 3.[180] J&J would need to conduct a new clinical study under an IDE, then obtain a lung-specific approval for FLEX—a process that could take several years.[181] Only then could Monarch obtain clearance for use with FLEX.[182]

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[175] JX 1182; JX 1171.

[176] Kozak Tr. 1572; *see* JX 1182 at 1.

[177] JX 1239.

[178] JX 1220; *see also* JX 1239; JX 6028.

[179] JX 1673 at 2.

[180] *Id.* at 1; Bryant Tr. 2490-91.

[181] Wittwer Tr. 1966-68; Wittwer Rep. ¶¶ 95-101.

[182] Wittwer Tr. 1967-68.

Moll was not told about the NeuWave patient death until shortly after the merger closed in early April 2019.[183]

J. The Merger Agreement

J&J's preliminary draft merger agreement included ten potential earnout milestones.[184] Two Monarch-specific milestones concerned 510(k) approval for certain indications, including lung tissue ablation.[185] Six milestones concerned iPlatform regulatory approvals for general surgery, a gastrointestinal (GI) surgery, and four to-be-determined "umbrella" procedures that Auris was to fill in.[186] There were also two net sales milestones.[187]

Auris sent back a revised draft of the merger agreement with revisions to the proposed milestones.[188] The Monarch lung tissue ablation milestone was changed to "soft tissue ablation," which Auris believed would not require clinical testing.[189] As for iPlatform, Auris proposed milestones in line with its MVP strategy that began with less complex procedures and built to more complex procedures.[190]

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[183] JX 1730; Moll Tr. 174.

[184] JX 5016 § 2.07.

[185] *Id.* § 2.07(a)(i)-(ii); *see supra* note 165 and accompanying text.

[186] JX 5016 § 2.07 (a)(iii)-(vii); DeFonzo Tr. 366-68.

[187] *Id.* § 2.07 (a)(ix)-(x).

[188] JX 1278; JX 1285.

[189] JX 1278 at 227; DeFonzo Tr. 361-63; JX 1334.

[190] DeFonzo Tr. 369; *see* JX 1620 (the "Merger Agreement") § 2.07(a).

All of the iPlatform milestones were for laparoscopic procedures, rather than more complex concomitant ones.[191] Auris insisted that approval of any "upper abdominal" and "lower abdominal" procedures by year end 2021 would satisfy the first iPlatform regulatory milestone.[192] This was in contrast to the "general surgery" indication suggested by J&J, which would have required Auris to demonstrate the safety and effectiveness for the most complex procedure in the "general surgery" umbrella.[193] The subsequent milestones matched specific umbrella procedures that Auris was targeting.[194] J&J accepted these changes.

The agreed-upon regulatory milestones for iPlatform were:

1. General Surgery Milestone: $400,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering, with a specific indication for one upper abdominal surgical procedure and one lower abdominal procedure" by the end of 2021 (the "General Surgery Milestone");[195]

2. Upper Abdominal Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . .

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[191] Merger Agreement § 2.07(a)(i)-(viii); *see* Moll Tr. 49-50.

[192] *See* JX 5016 at 3-4; Merger Agreement § 2.07(a)(iii); DeFonzo Tr. 365-67.

[193] DeFonzo Tr. 364-65; *compare* JX 5016 § 2.07(a)(iii) (J&J draft proposing regulatory approval on iPlatform "for general surgery procedures"), *with* Merger Agreement § 2.07(a)(iii) (final version requiring iPlatform regulatory approval for "one upper abdominal surgical procedure and one lower abdominal surgical procedure").

[194] DeFonzo Tr. 366-68; *compare* JX 5016 § 2.07(a)(iv)-(vii) (J&J leaving brackets for umbrella milestones for Auris to fill in), *with* Merger Agreement § 2.07(a)(iv)-(vii) (listing specific indications).

[195] Merger Agreement § 2.07(a)(iii).

upper abdominal Umbrella Procedure(s)" by the end of 2023 (the "Upper Abdominal Milestone");[196]

3. Colorectal/Lower Abdominal Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . urological Umbrella Procedure(s)" by the end of 2023 (the "Lower Abdominal Milestone");[197]

4. Urologic Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . colorectal/lower abdominal Umbrella Procedure(s)" by the end of 2023 (the "Urologic Milestone");[198] and

5. Gynecologic Surgery Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . gynecological Umbrella Procedure(s)" by the end of 2023 (the "Gynecologic Milestone").[199]

The Monarch-related milestones were:

6. Endourology Milestone: $100,000,000 if Monarch obtained "510(k) premarket notification(s) allowing marketing and sale of a Monarch Product offering, with a specific indication for endourology procedure(s)" by the end of 2020 (the "Endourology Milestone");[200] and

7. Robotic Soft Tissue Ablation Milestone: $100,000,000 if Monarch obtained "510(k) premarket notification(s) allowing

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[196] *Id.* § 2.07(a)(iv). "Umbrella Procedure" is defined as "any procedure or procedure category within a specialty, which represents higher complexity or risk and when cleared by the FDA includes covered procedures of less complexity or lower risk within that specialty." *Id.* § 10.03(uuu).

[197] *Id.* § 2.07(a)(v).

[198] *Id.* § 2.07(a)(vi).

[199] *Id.* § 2.07(a)(vii).

[200] *Id.* § 2.07(a)(i).

marketing and sale of a Monarch Product offering, with a specific indication for robotically driven (or controlled) soft tissue ablation" by the end of 2022 (the "Soft Tissue Ablation Milestone").[201]

An additional regulatory milestone could be satisfied by either iPlatform or Monarch:

8. Robotic GI Endoluminal Milestone: $150,000,000 if either iPlatform or Monarch obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering (or, alternatively . . . a Monarch product offering), with a specific indication for procedure(s) specifically including Endoscopic Submucosal Dissection (ESD)" by the end of 2023 (the "GI Milestone").[202]

Finally, there were two commercial milestones that could be satisfied by either Verb or Auris products:

9. First Step Net Sales Milestone: $500,000,000 if Robotics Net Sales before the end of 2022 reached or exceeded "$575 million in the aggregate";[203] and

10. Second Step Net Sales Milestone: $500,000,000 if Robotics Net Sales before the end of 2022 reached or exceeded "$575 million in the aggregate."[204]

Auris's markup of the draft merger agreement proposed a one-way anti-reliance clause favoring Auris. It also included a provision that would obligate J&J to take efforts to develop and commercialize the Auris robots consistent with "a

[201] *Id.* § 2.07(a)(ii).

[202] *Id.* § 2.07(a)(viii).

[203] *Id.* § 2.07(a)(ix).

[204] *Id.* § 2.07(a)(x).

company in the medical devices industry of comparable size and resources to J&J."[205] Auris had Intuitive in mind as the measure of industry standard efforts.[206]

J&J accepted the one-way anti-reliance clause but proposed an inward-facing efforts provision.[207] The efforts supplied were to be measured by J&J's own standards, which J&J assured Auris was beneficial since J&J was "the biggest healthcare company in the world" with standards exceeding the industry.[208] J&J agreed that these "commercially reasonable efforts" would be to the end of achieving the iPlatform and Monarch regulatory milestones.[209] As a residual assurance, Auris negotiated for language that tied J&J's efforts to its "usual practice" for "priority medical device products."[210]

The final Merger Agreement was executed on February 12, 2019 by Ethicon, Antwerp Merger Sub, Inc., Auris, and Fortis as the Auris stockholders' representative.[211] At the time, Auris had a high level of confidence in achieving regulatory clearance via the 510(k) pathway, in iPlatform's and Monarch's ability to

[205] JX 1278 at 159, 232; *see* DeFonzo Tr. 381-82.

[206] DeFonzo Tr. 381.

[207] *Id.* at 381-83; *see also* Hinchliffe Tr. 3145-46; Hinchliffe Dep. 206-07.

[208] DeFonzo Tr. 382.

[209] Merger Agreement § 2.07(e)(i), (ii); *see* Shen Tr. 1152.

[210] Merger Agreement § 2.07(e)(ii); *see* DeFonzo Tr. 382-83; Hinchliffe Tr. 3145-46.

[211] PTO ¶ 111.

deliver on the milestones, and a shared vision with J&J for the robots.[212] The merger was set to close on April 1.

K. Pre-Closing Preparations

Verb continued to struggle. McEvoy told Gorsky as much on March 10, prompting Gorsky to ask why Verb's timelines "continue to change with multiple explanations for delays and issues."[213] To address Gorsky's concerns, Shen proposed an "assessment between Verb and iPlatform from a portfolio perspective."[214] Celine Martin, who oversaw J&J's robotics and digital surgery program, was "aligned" with the proposal.[215]

Shen's "worry" about "Verb vs. iPlatform" was that the "Verb team [would] know [the J&J's leadership team's] hesitation."[216] As he told McEvoy, they must be "all in for Verb."[217] Shen believed that "Verb + iPlatform [wa]s [J&J's] bullet proof strategy to compete."[218] As he wrote on the day the Auris merger closed: "Delivering of Verb milestones is our No. 1 priority."[219]

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[212] DeFonzo Tr. 363-64; Gardiner Tr. 748-61.

[213] JX 1581; *see also* JX 1590 at 2; Shen Tr. 1112-14.

[214] JX 1581 at 1.

[215] *Id.*

[216] JX 1630.

[217] *Id.*

[218] *Id.*

[219] JX 1663; *see* Shen Tr. 1152, 1308. During his testimony, Shen said that this was "not false." Shen Tr. 1308.

L. Project Manhattan

Four days after closing, Shen drafted a "Plan to Technically Assess Verb Platform and iPlatform."[220] He wrote that the objective was "to assess the robotic system (Digital Surgery) development status from Verb and Auris and recommend an optimal path to bring the system(s) to market, considering factors such as launch schedule, project risk identification and mitigation, specialty indication launch cadence, surgeon preference, etc."[221] He described three possible outcomes. First, J&J could "[d]evelop both systems in parallel and the[n] make the final commercialization decision." Second, it could "[c]hoose one of the two" systems. Or, third, it could "[m]erge them into a single development by combining the best of each."[222]

Shen sent a draft of the plan to Martin, writing: "I am still thinking about how we do this highly sensitive assessment work. We cannot lose [the] Verb team at this point."[223] He also sent a draft to Kilroy—Verb's lead engineer. Kilroy envisioned

[220] JX 1702.

[221] JX 1703.

[222] JX 1702.

[223] JX 1703.

that the robots would be merged into a combined system.[224] He suggested that Shen revise "framing the project objective in a way that is less controversial."[225]

Shen then edited the document. The new version stated that the objective of the assessment was to "find synergies between platforms to decrease project risk and accelerate time to commercialization."[226] He removed the description of the three post-assessment "potential scenarios" outlined in his prior draft.[227] He titled the assessment "Project Manhattan."[228]

Shen sent the revised version to Moll on April 9.[229] Moll was aghast. During negotiations, J&J had told Auris it would perform a post-closing "technology audit" to understand Auris's systems and ways that J&J's "global candy store" of resources could be beneficial to Auris.[230] DeFonzo's discussions with J&J similarly led him to understand that a "technology audit" would be conducted to understand "technologies available within Ethicon unrelated to Verb" that could help Auris."[231]

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[224] Kilroy Tr. 2143; Kilroy Dep. 43-44.

[225] JX 1710.

[226] JX 1725 at 2.

[227] JX 1703 at 2; *see* JX 1725.

[228] JX 1725. "Manhattan" was an internal code name for Verb. *See* JX 2833 (discussing "Manhattan" as "Verb"); Lenard Tr. 1799; JX 2658 at 1.

[229] JX 1719; JX 1725. The version sent to Martin and Kilroy was never shared with Moll.

[230] Moll Tr. 47-48.

[231] DeFonzo Tr. 400-01.

But a comparative assessment between Verb and iPlatform had not been mentioned.[232]

On April 22, Shen formally introduced Project Manhattan to the Verb and Auris teams, describing it as a "Technical Assessment of Verb Surgical Platform and Auris iPlatform."[233] He said that a "deep dive assessment" would be conducted "in the following areas" for each platform:

- Master controller or [user input device]
- Robotic components and systems
- Instrumentation
- Visualization system
- Data connectivity
- Machine learning and [d]ata analytics.[234]

Shen said that Project Manhattan would be "co-le[d]" by Kilroy and Mintz and completed over the "next 60-70 days."[235]

Moll promptly told Shen of his concern that "[s]upporting a complex and detailed 90 day technical review by all Auris technical heads w[ould] affect [Auris's] ability to stay on schedule."[236] Shen responded that "the system should stay as it is (no need to be dressed up) for review."[237] By this point, though, Moll and the Auris

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[232] *See* Moll Tr. 70-72; JX 1500.

[233] JX 1813; *see* Shen Tr. 1158.

[234] JX 1813 at 1-2.

[235] *Id.*

[236] JX 1830; *see* Moll Tr. 76.

[237] JX 1838.

team had learned that J&J capped the robotics budget (i.e., the Ashley Management Decision), leading them to doubt that Verb and iPlatform would be developed on "parallel path[s]."[238] It seemed to them that Project Manhattan was a "bakeoff" between Verb and iPlatform.[239] The Auris team feared that only one robot could win; the loser would be deprioritized, deemphasized, and cease to exist.[240]

Auris's suspicions were well placed. Amid Project Manhattan, Martin wrote that she did not "see [J&J] running parallel path [V]erb-Auris all the way to 510k" because "P&L will not support it and it is very inefficient."[241] An internal J&J retrospective document from the next year recognized that "[Project Manhattan was [a] financial necessity[]" given the significant expense of "[d]eveloping 2 complex robots at the same time."[242] The probable end goal was to find ways to "mesh" the robots, consistent with Gorsky's earlier aspirations and the budget set by the Ashley Management Decision.[243]

Auris leadership thus viewed Project Manhattan as an existential threat to iPlatform. Because the months-old iPlatform alpha robot would be pitted against a

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[238] Moll Tr. 76; *id.* at 47-48; Mintz Tr. 586-87.

[239] Moll Tr. 72; DeFonzo 403-06.

[240] Moll Tr. 72.

[241] JX 1947.

[242] JX 2774 at 5.

[243] *See supra* notes 114, 156-57 and accompanying text; JX 2656; Lenard Day 2 Dep. 23-24.

Verb post-beta robot that had been through years of iterations, Auris had to quickly prepare to "survive."[244] Mintz focused on creating "workarounds" for system "bugs," which he described as "the engineering and software equivalent of Band-Aids, duct tape, and baling wire."[245] iPlatform incurred a significant "technical debt" from going "backwards rather than forwards in development [] to prop up a system" for an unanticipated head-to-head evaluation.[246] In exchange for short term stability to compete against Verb, iPlatform largely suspended its development plan, MVP strategy, and beta version progress.[247]

Project Manhattan consisted of seven procedures performed by eight "key opinion leader" surgeons ("KOLs"). Most of the KOLs were experienced on the Verb device but had never used iPlatform.[248] Two of the KOLs had worked closely on Verb's development.[249] The procedures performed were: Roux-en-Y gastric bypass (RYGB), low anterior resection (LAR), ventral hernia, partial nephrectomy,

[244] Mintz Tr. 588-89

[245] *Id.* at 589.

[246] Moll Tr. 76; Mintz Tr. 590.

[247] *See* Mintz Tr. 587-88; JX 1793.

[248] JX 2125 at 2.

[249] These KOLs were Dr. Monika Hagen and Dr. Keith Kim. Hagen Tr. 2282; Hagen Dep. 16-18; Kim Dep. 28, 28-49. Moll asked that Gardiner, who was experienced with iPlatform, be a KOL. His request was rejected. Mintz Tr. 594-95; Moll Dep. 633-34.

hysterectomy, and lobectomy.[250] After the procedures, the KOLs rated each system's capabilities.[251]

Both iPlatform and Verb successfully completed all seven procedures.[252] The KOLs gave iPlatform positive feedback and rated the system somewhat or nearly ready for clinical use, with the exception of lobectomy.[253] iPlatform's performance in one RYGB lab and the hysterectomy lab were rated equal to that of da Vinci.[254]

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[250] JX 2103; JX 2125; JX 2131. RYGB surgery, also called bariatric surgery, reduces the size of the stomach and reroutes part of the small intestine. LAR surgery treats rectal cancer by removing part of the rectum and reconnecting the rectum to the colon. Ventral hernia surgery repairs protrusions of the intestine or other tissue through the abdominal wall. Partial nephrectomy involves remoting a portion of the kidney to treat disease or injury. A hysterectomy is a procedure to remove the uterus. A lobectomy is a procedure to remove a lobe of the lung, including to treat cancer. *See* Stanford Medicine, *General Surgery – Common Surgical Procedures*, Stanford Health Care, https://stanfordhealthcare.org/medical-treatments/g/general-surgery/procedures.html) (last visited Aug. 31, 2024); *Roux-en-Y Gastric Bypass Weight-Loss Surgery*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/rouxeny-gastric-bypass-weightloss-surgery (last visited Aug. 31, 2024); Timothy J. Ridolfi, MD et al, *Low Anterior Resection Syndrome: Current Management and Future Directions*, 29 Clinics in Colon and Rectal Surgery 239, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4991969/; *Nephrectomy (kidney removal)*, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/nephrectomy/about/pac-20385165 (last visited Aug. 31, 2024); *Lobectomy*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/lobectomy (last visited Aug. 31, 2024).

[251] Mintz Tr. 594-95.

[252] *Id.* at 592-98; JX 2125; JX 1878.

[253] JX 2131.

[254] *Id.* at 26-28.

The hysterectomy lab was a breakthrough for the iPlatform team, since it marked the first time a surgeon was able to perform a procedure using all six robotic arms.[255]

Overall, the KOLs "were confident that both systems w[ould] be clinically capable."[256] Although they raised problems with iPlatform (and Verb), the Auris team left Project Manhattan feeling encouraged with iPlatform's performance.[257] The first iPlatform milestone (the General Surgery Milestone) was still 2.5 years away, with subsequent milestones to be completed in 4.5 years.

M. iPlatform "Wins" the Bake-Off

On June 16, 2019, Martin reported to McEvoy and other J&J leaders that iPlatform "performed well and managed to complete" all KOL procedures.[258] By this point, Martin and Shen had agreed that parallel pathing both robots would be an unsuccessful strategy.[259] They believed that only one system should be brought to market. After considering KOL feedback, along with the vision and unique features of iPlatform, Shen and Martin recommended to McEvoy that J&J prioritize iPlatform.[260]

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[255] Mintz Tr. 596-98; *see* Pl.'s Trial Demonstrative ("Pl.'s Dem.") 8 (video of the lab being performed).

[256] JX 2131 at 18.

[257] Moll Tr. 80; Mintz Tr. 598-600.

[258] JX 2103.

[259] JX 2144.

[260] JX 2164; JX 2236.

But "go[ing] with iPlatform" did not mean abandoning Verb.[261] Consistent with J&J's goals and budget, Shen, Martin, and others discussed combining the systems instead.[262] Shen thought that "[c]ombining 2 programs into 1 ma[de] all the sense from [a] traditional development standpoint – focus, budget, priority" to compete with Intuitive.[263]

The J&J team prepared a recommendation to Gorsky, which projected iPlatform 2019, 2020, and 2021 launch dates and a Verb launch date sometime after 2021.[264] A slide showing the technical synergies between iPlatform and Verb identified where iPlatform parts could be "plan B option[s]" should Verb's development stall.[265] Gorsky asked that more elements of Verb be added to iPlatform.[266]

In late September, Martin recommended to Gorsky that J&J pursue a combination system of iPlatform "augmented by incremental [V]erb capabilities

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[261] JX 2164.

[262] JX 2180.

[263] *Id.*

[264] JX 2275 at 32.

[265] *Id.* at 45.

[266] DeFonzo Tr. 408-09 ("Celine informed me sometime in mid-July that Alex had asked the team to go back and find more elements of Verb to include in the iPlatform."). Martin could not remember this discussion, or most of the other deliberations from this period. *See* Martin Tr. 1684-1689. DeFonzo's testimony was overall credible, supported by Gorsky's hope of meshing the robots, and the subsequent events.

incl[uding] the Verb surgeon console."[267] Gorsky questioned why the financial valuations for Verb and iPlatform were higher separately than when the systems were combined and noted that the combination would "lead[] to some delay."[268] When McEvoy asked for clarification, J&J Chief Financial Officer Flavia Pease explained that the lower valuation "still assumes all Auris milestones being paid in full" and offered to "discuss further live."[269] McEvoy subsequently told Gorsky that the combined Verb/iPlatform valuation improved "when you consider what will also happen with contingent payment"—meaning the earnout.[270] Gorsky gave the team the "green light" to proceed with next steps.[271]

N. The FDA's New Pathway Guidance

Despite the challenges of Project Manhattan, Auris strove to get iPlatform back on track for regulatory approval. On June 28, Auris sent the FDA a pre-submission for iPlatform with RYGB and inguinal hernia repair indications.[272]

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[267] JX 2594 at 20; Martin Tr. 1683-84.

[268] JX 2599.

[269] *Id.*

[270] JX 2606; McEvoy Tr. 2637; McEvoy Dep. Day 2 207-08; *see also* JX 2584 at 26.

[271] Martin Tr. 1693.

[272] JX 2328 at 43. A laparoscopic inguinal hernia procedure repairs a hernia in the groin area through small incisions. *See Inguinal hernia*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/inguinal-hernia/diagnosis-treatment/drc-20351553 (last visited Aug. 31, 2024).

Auris also selected a different da Vinci predicate device than the one it had listed in its prior submission to address the FDA's initial feedback.[273]

In a Verb-related meeting with the FDA on August 5, J&J learned that "going forward," the agency believed that the 510(k) pathway would be closed for any new RASD.[274] The FDA reached this decision due to the systems' "complexity" and difficulties "mak[ing] a substantial equivalence determination" for a predicate device.[275] The FDA "indicated" that the "De Novo pathway [wa]s still a potential option" versus the more complex PMA pathway.[276] In assessing the effect of this pathway change on Verb's launch schedule, J&J's regulatory team concluded that De Novo review would yield "[n]o significant timeline differences compared to a 510(k)" review.[277]

The next month, the FDA notified J&J that the 510(k) pathway was likewise closed to iPlatform.[278] On January 6, 2020, the FDA confirmed that iPlatform could seek approval through the De Novo pathway instead of PMA.[279] This was seen as a

[273] JX 2328 at 46; *see supra* notes 70-72 and accompanying text.

[274] JX 2512 at 5.

[275] *Id.*

[276] *Id.*

[277] JX 2396 at 12-13.

[278] JX 6116 at 4; *see also* JX 2620; JX 6117.

[279] JX 2951 at 6; Shen Tr. 1174; *see also* JX 2396 at 2; Bryant Tr. 2514-16.

positive outcome.[280] It was still within the five-month buffer built into iPlatform's timeline to achieve its 2021 General Surgery Milestone, not to mention the longer timelines for the 2023 milestones.[281] And once iPlatform obtained De Novo approval, it could use the 510(k) pathway for future indications by serving as its own predicate device.[282]

O. Manhattan

On December 5, 2019, J&J management recommended to the J&J Board that the company proceed with "a combined platform where Auris' iPlatform is augmented by Verb assets including the open surgeon console, intra-procedure data capabilities and the surgeon portal."[283] The combination robot, called "iPlatform+," was described as a "[n]ext generation robotic platform designed with more flexibility, more control, and more information to elevate [the] surgeon experience [and] improve patient care."[284]

As part of the combination plan, the J&J Board approved a full acquisition of Verb by buying out residual assets from Verily.[285] On December 19, J&J "signed

[280] *See* Shen Tr. 1174.

[281] JX 1689 at 13.

[282] JX 2396 at 12.

[283] JX 2732 at 4; *see* Martin Tr. 1693.

[284] JX 2800 at 4.

[285] JX 2732 at 4.

the Manhattan (Verb) option agreement."[286] J&J "execute[d] Manhattan" on February 19, 2020 for a purchase price of approximately $155 million.[287]

Afterward, J&J worked to integrate Verb's resources into Auris. The Auris leadership team was largely sidelined. A "[f]ull [s]peed [m]igration" of more than "200 [Verb] employees" to the iPlatform team commenced.[288] A calamity of excess and redundancy resulted.[289] Hostility abounded between the two factions, which had just faced off in Project Manhattan for the survival of their respective projects.[290] J&J soon announced layoffs on both teams.[291]

Within a year of the integration, every engineer from legacy Auris's iPlatform clinical engineering team left the company—a "devastating" loss for the program.[292] Meanwhile, Verb software engineers insisted on re-writing iPlatform's code.[293] Significant attrition of legacy Auris software engineers followed.[294]

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[286] JX 2833 ("Manhattan signed!").

[287] JX 3407; JX 2656 at 1.

[288] JX 2743 at 11; *see* Mintz Tr. 609-11.

[289] JX 3094.

[290] JX 2743 at 11; DeFonzo Tr. 425-427; *see also* JX 2991 at 4.

[291] JX 3272 at 12; JX 3280.

[292] Mintz Tr. 616-17.

[293] *Id.* at 613-14; JX 3194.

[294] Pl.'s Dem. 7; Mintz Tr. 612-615.

P. The Milestone Write-down

In April 2020, J&J internally wrote down the value of the iPlatform and GI regulatory milestones to zero.[295] J&J also wrote down the net sales milestones.[296] These write-downs created an on-the-books profit of $983.6 million for J&J.[297] An internal memo stated that the write-down was prompted by the FDA's shift from the 510(k) to the De Novo pathway for iPlatform.[298]

J&J publicly announced the write-down on April 14.[299] Auris leadership learned about the write-downs around that time.[300] McEvoy and Shen told Moll that change was a result of the FDA's pathway change.[301] Fortis sent J&J an information request, and J&J issued a litigation hold on April 24.[302]

With the milestones written off and litigation looming, J&J instituted a "new reality" for Auris.[303] Martin and her team rolled out an employee incentive plan that

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[295] JX 3139; Shen Tr. 1171; Lenard Tr. 1827-28. Internal communications suggest that J&J finance leaders had been considering the potential effects of writing down the milestones since October 2019. *See* JX 2675.

[296] JX 3139.

[297] *Id.*; *see also* JX 5149 at 26.

[298] JX 3139. Draft talking points for a first quarter earnings call referred to the milestone-related profit as a "material" amount of money to the company. JX 3112 at 9.

[299] JX 3168; PTO ¶ 161.

[300] Moll Tr. 95-96; Mintz Tr. 617. DeFonzo learned about the milestones from Martin a day before the announcement. DeFonzo Tr. 428.

[301] JX 3193; Moll Tr. 95-96, 195, 198; *see also* JX 3253; Lenard Tr. 1830; JX 3392 at 15.

[302] JX 5015; Shen Tr. 1174-75; JX 4490 at 9-10.

[303] Moll Tr. 95.

had been first discussed in late 2019.[304] The revised employee "milestones" included bonuses upon iPlatform receiving FDA approval for "general surgery," which was different from the first iPlatform regulatory milestone in the Merger Agreement.[305] The new incentive plan lacked any incentives for umbrella procedures and all GI-related incentives were removed.[306]

Two months after the write-down of the iPlatform regulatory and GI milestones, J&J announced the formation of a "Tiger Team" to simplify iPlatform's reporting structure.[307] The iPlatform operational team was to report to Steve Joachim, who effectively replaced Mintz.[308] Joachim was a leader of the Ethicon instrument development group that supported J&J's robotics program.[309] A systems engineer by training, he lacked prior experience with RASDs.[310]

J&J also invested significant financial resources into the iPlatform/Verb program.[311] By the end of November, McEvoy had requested $200 million to

[304] JX 2675 at 1; Moll Tr. 95-97; Mintz Tr. 617-18.

[305] JX 3641 at 3-4; DeFonzo Tr. 430-32; Pl.'s Dem. 6.

[306] *See* Pl.'s Dem. 6.

[307] JX 3363 at 5; JX 3391 at 9.

[308] JX 3391 at 10.

[309] JX 2233 at 2; Joachim Tr. 2156-57.

[310] Joachim Tr. 2157, 2241; Mintz Tr. 618-19.

[311] JX 3417 at 6, 8-9; JX 3465 at 13; Lenard Tr. 1858-62.

develop the combined system.[312] J&J's allocation of resources to iPlatform 16 months post-merger proved too little, too late.

Q. This Litigation

On October 12, 2020, Fortis Advisors LLC filed a Verified Complaint against J&J, Ethicon, Gorsky, McEvoy, Shen, and Morano.[313] Fortis brought the suit in its capacity as the representative of former Auris stockholders. It advanced 12 causes of action, including equitable fraud, common law fraud, breach of the Merger Agreement, reformation, mutual mistake, civil conspiracy, breach of the implied covenant of good faith and fair dealing, and specific performance.

R. J&J's New Narrative

The iPlatform beta prototype—the second iteration of the full system—came online at the end of 2020.[314] Auris had planned to go to clinical trials with, obtain FDA clearance for, and launch the beta version of iPlatform.[315] The system experienced technical complications, including thermal, stability, and workspace issues.[316] These were issues Auris had been aware of during the alpha iteration and viewed as "imminently solvable" until progress was derailed by Project

[312] JX 5231 at 20.

[313] Dkt. 1.

[314] JX 4181.

[315] Mintz Tr. 662-63.

[316] *Id.* at 619-20; Khan Tr. 3021; JX 3764 at 10-11, 21, 66, 83.

Manhattan.[317] The integration of the Verb system created an added layer of stability complications for iPlatform.[318]

A new account of the Auris acquisition began to emerge at J&J. In March 2021, Shen sent Joachim an email titled "Very important thinking" that attached a "narrative document" outlining Shen's own "reflection" on iPlatform.[319] Shen wrote that the "original plan was to launch the Verb system first, giving [iPlatform] [a] 3-year time[line] to fully prove concept feasibility."[320] Shen noted that J&J's "current challenge" with iPlatform was due to "design problems," including "Work Space (Reach, Access and Collision Prevention, etc.)."[321]

In early May, Joachim circulated a deck to J&J leadership citing technical issues as the reason for iPlatform program delays.[322] Joaquin Duato, who replaced Gorsky as CEO in early 2022, asked why Shen had been unaware of iPlatform workspace issues sooner.[323] Joachim began searching old due diligence files,

[317] Mintz Tr. 619-22.

[318] *Id.* at 686.

[319] JX 3814 at 1. The presentation referred to iPlatform as "Ottava," which was the robot's name at this point.

[320] *Id.* at 5.

[321] JX 3814 at 5.

[322] JX 5036.

[323] JX 5247 at 1.

focusing on reports about arm design.[324] The pre-merger design choice Auris engineers made between so-called "Silverton" and "Superton" style robotic arms was cast as evidence of Auris's deceit during due diligence.[325]

By the end of 2021, iPlatform was shelved.[326] J&J pivoted to a system utilizing Verb's bed-based architecture combined with certain iPlatform components and accessories.[327]

S. Litigation Continues

While iPlatform sat idle, Fortis's litigation proceeded apace.

On December 13, 2021, Fortis's equitable fraud, reformation, and civil conspiracy claims were dismissed.[328] Individual defendants Gorsky, McEvoy, Shen, and Morano were also dismissed for lack of personal jurisdiction.[329]

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[324] JX 3960.

[325] JX 6149; Shen Tr. 1289-90; McEwen Dep. 161-62; Joachim Tr. 2218-19; Mintz Tr. 718.

[326] JX 4322 at 2.

[327] *Id.*

[328] Dkt. 102.

[329] *Id.*

A ten-day trial began on January 16, 2024.[330] Just before trial began, Fortis voluntarily dismissed its mutual mistake and unjust enrichment claims.[331] Post-trial briefing and argument were completed on May 22, 2024.[332]

II. ANALYSIS

Fortis advances both contract and fraud claims against J&J. Its contract-based contentions include that J&J repudiated and breached the Merger Agreement and breached the implied covenant of good faith and fair dealing. As to fraud, Fortis argues that J&J deceived Auris into merging and accepting a contingent payment for the Monarch Soft Tissue Ablation Milestone.

I begin with the contract theories. Fortis proved that J&J breached its efforts obligation and the implied covenant regarding the iPlatform regulatory milestones but not the Monarch-related or net sales milestones. It did not prove that J&J repudiated the Merger Agreement.

As to its fraud theories, Fortis met its burden regarding J&J's statements about the Monarch Soft Tissue Ablation Milestone. It did not prove that J&J's more general statements about future intentions for Auris amount to fraud.

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[330] Dkt. 539.

[331] Dkts. 527-28.

[332] Fortis Advisors LLC's Opening Post-trial Br. (Dkt. 561) ("Pl.'s Opening Post-trial Br."); Defs.' Answering Post-trial Br. (Dkt. 562); Fortis Advisors LLC's Reply Post-trial Br. (Dkt. 566); *see also* Dkts. 571-72.

Fortis is entitled to damages for the breach of contract, implied covenant, and fraud claims on which it prevails. Damages total $1,011,271,21.009, inclusive of pre-judgment interest for milestones that expired before trial and exclusive of pre-judgment interest owed since then.

A. Breach of Contract

"Under Delaware law, the elements of a breach of contract claim are: 1) a contractual obligation; 2) a breach of that obligation by the defendant; and 3) resulting damage to the plaintiff."[333] Fortis has the burden to prove each element by a preponderance of the evidence.[334] "Proof by a preponderance of the evidence means proof that something is more likely than not."[335]

"A contract's express terms provide the starting point in approaching a contract dispute."[336] "Delaware law adheres to the objective theory of contracts," meaning that "a contract's construction should be that which would be understood by an objective, reasonable third party."[337] "When interpreting a contract, [the]

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[333] *H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 140 (Del. Ch. 2003).

[334] *Narayanan v. Sutherland Global Hldgs. Inc.*, 2016 WL 3682617, at *8 (Del. Ch. July 5, 2016) (citing *Agilent Techs., Inc. v. Kirkland*, 2010 WL 610725, at *13 (Del. Ch. Feb. 18, 2010)).

[335] *inTEAM Assoc., LLC v. Heartland Payment Sys., Inc*., 2016 WL 5660282, at *13 (Del. Ch. Sept. 30, 2016)), *aff'd in part, rev'd in part on other grounds sub nom. Heartland Payment Sys., LLC v. Inteam Assocs., LLC*, 171 A.3d 544 (Del. 2017).

[336] *Ostroff v. Quality Servs. Labs., Inc.*, 2007 WL 121404, at *11 (Del. Ch. Jan. 5, 2007).

[337] *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citation omitted).

Court 'will give priority to the parties' intentions as reflected in the four corners of the agreement.'"[338] "Absent some ambiguity, Delaware courts will not distort or twist contract language under the guise of construing it."[339] These principles guide my review of the Merger Agreement.

1. The Earnout Structure

Fortis, on behalf of Auris's former stockholders, seeks recovery of the contingent consideration memorialized in the Merger Agreement. Auris received $3.4 billion in cash at closing.[340] Its stockholders stood to gain another $2.35 billion in earnout payments, $1.15 billion of which was conditioned on iPlatform obtaining regulatory approval for increasingly complex procedures by staged deadlines.[341]

"An earn-out is a provision in an acquisition agreement that makes a portion of the purchase price payable to the seller if/when certain post-closing performance targets are achieved."[342] It is a popular means to bridge price gaps between buyers

[338] *Salamone v. Gorman*, 106 A.3d 354, 368 (Del. 2014) (quoting *GMG Cap. Inv., LLC v. Athenian Venture P'rs I, L.P.*, 36 A.3d 776, 779 (Del. 2012)).

[339] *Allied Cap. Corp. v. GC-Sun Hldgs., L.P.*, 910 A.2d 1020, 1030 (Del. Ch. 2006). Neither party argues that the relevant provisions of the Merger Agreement are ambiguous, and I find no ambiguity.

[340] Merger Agreement §§ 2.03(a)(ii), 10.03(l), 10.03(w).

[341] *Id.* § 2.07(a).

[342] Richard De Rose, *The Ins and Outs of Earn-Outs: A Delaware Perspective*, ABA Business Law Today (Mar. 2022), https://www.americanbar.org/groups/business_law/resources/business-law-today/2022-march/the-ins-and-outs-of-earn-outs-a-delaware-perspective/.

and sellers, with different considerations for each.[343] Buyers can mitigate valuation risk since the contingent payment is based on the seller's actual future performance rather than its projections. Sellers give up guaranteed cash but stand to gain a greater payment overall than they might otherwise receive upfront if defined milestones are met.

A key point of tension in negotiating an earnout structure is allocating post-closing operational control.[344] The buyer prefers to freely manage the post-closing activities of the business and to minimize earnout payments. For the buyer, a favorable approach grants it the right to operate the business in its sole discretion, limited only by good faith.[345] The seller, by contrast, would rather retain a say in the acquired business and to maximize earnout payments. It may bargain for a contractual assurance that the buyer will devote certain "efforts" toward meeting the milestones.[346]

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[343] JX 3955 at 4 (Leonidas G. Barbopoulos & Jo Danbolt, *The Real Effects of Earnout Contracts in M&As*, 44 J. Fin. Rsch., 607, 610 (2010) (citation omitted)).

[344] *See* JX 4046 at 3-4 (Richard Harroch, *Understanding Earnouts in Mergers and Acquisitions*, Forbes (June 26, 2021), https://forbes.com/sites/allbusiness/2021/06/26/understandingearnoutsin-mergers-and-acquisitions/).

[345] *See, e.g.*, *LaPoint v. AmerisourceBergen Corp.*, 2007 WL 2565709, at *10 (Del. Ch. Sept. 4, 2007) (considering a provision requiring that the buyer "act in good faith during the Earnout Period" and not "undertake any actions during the Earnout Period any purpose of which is to impede the ability of the [seller's] [s]tockholders to earn the Earnout Payments").

[346] *See Himawan v. Cephalon, Inc.*, 2024 WL 1885560, at *7 (Del. Ch. Apr. 30, 2024) (discussing a buyer-friendly efforts standard where the buyer was given "complete discretion with respect to all decisions" related to purchased asset, limited only by an

"Variations on the 'efforts' concept include commitments to make: 'good faith efforts,' 'commercially reasonable efforts,' 'reasonable efforts,' 'reasonable best efforts' and 'best efforts.'"[347] From a transactional standpoint, these variations reflect "a hierarchy from lowest (good faith efforts) to highest (best efforts) level of commitment."[348] This is logical as a matter of plain English since the words used have different meanings.[349] But there is no agreement in case law over whether they create different standards. Delaware courts have viewed variations of efforts

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obligation to use commercially reasonable efforts to earnout milestones); *see also Neurvana Medical, LLC v. Balt USA, LLC*, 2020 WL 949917, at *15-16 (Del. Ch. Feb. 27, 2020) (interpreting an asset purchase agreement that gave the buyer "sole discretion and authority post-closing" to make decisions about a product, which discretion was limited by an "outward facing" commercially reasonable efforts requirement).

[347] Peter Atkins & Edward Micheletti, "'Reasonable Efforts' Clauses in Delaware: One Size Fits All, Unless . . . ," Harvard Law School Forum on Corporate Governance (Nov. 22, 2018), https://corpgov.law.harvard.edu/2018/11/22/reasonable-efforts-clauses-in-delaware-one-size-fits-all-unless/ (last visited Aug. 30, 2024).

[348] *Id.*; *see also* 1 ABA Mergers and Acquisitions Committee, *Model Stock Purchase Agreement with Commentary* 212 (2d ed. 2010) (describing a "general sense of hierarchy of various types of efforts clauses"); 2 Lou R. Kling et al., *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* § 13.06 (2024) ("[M]ost practitioners treat 'reasonable efforts,' 'commercially reasonable efforts' and 'reasonable best efforts' as all different from, and as imposing less of an obligation than, 'best' efforts. There is no universal agreement, however, as to whether these three standards are, as a practical matter, any different from each other; notwithstanding the fact that 'reasonable best efforts' *sounds* as if it imposes more of an obligation than 'commercially reasonable efforts.'").

[349] *E.g.*, *Best*, Merriam-Webster, https://www.merriam-webster.com/dictionary/best (last visited Aug. 31, 2024) (defining "best" as "excelling all others" or "most productive of good; offering or producing the greatest advantage, utility, or satisfaction"); *Reasonable*, Merriam-Webster, https://www.merriam-webster.com/dictionary/reasonable (last visited Aug. 31, 2024) (defining "reasonable" as "being in accord with reason" or "moderate, fair").

clauses—particularly those using the term "reasonable"—as largely interchangeable.[350]

More important, then, is carefully drafting language that delineates the efforts expected of the buyer relative to the achievement of the milestones. The parties can set an outward facing efforts definition that looks to an industry standard or other industry participants as a yardstick.[351] This is generally seller friendly because the seller can cite external standards by which to measure the buyer's efforts. Alternatively, the parties can set an inward facing definition, which applies the

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[350] *See Williams Cos., Inc. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 272 (Del. 2017) (holding that "commercially reasonable efforts" and "reasonable best efforts" both "impose obligations to take all reasonable steps to solve problems and consummate the transaction"); *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *87 (Del. Ch. Oct. 1, 2018) (observing the lack of support in case law "for the distinctions that transactional lawyers draw" between the various efforts clauses), *aff'd*, 198 A.3d 724 (Del. 2018) (TABLE); *Channel MedSystems, Inc. v. Boston Sci. Corp.*, 2019 WL 6896462, at *37 n.410 (Del. Ch. Dec. 18, 2019) (noting that a "commercially reasonable efforts" provision is functionally the same under Delaware law as a "reasonable best efforts provision" (citing *Akorn*, 2018 WL 4719347, at *87 & n.796)); 1 ABA Mergers and Acquisitions Committee, *Model Stock Purchase Agreement with Commentary* 213 ("[C]ase law offers little support for the position that 'reasonable best efforts,' 'reasonable efforts,' or 'commercially reasonable efforts' will be interpreted as separate standards less demanding than 'best efforts.'").

[351] *See* Kristian A. Werling & Richard B. Smith, "Commercially Reasonable Efforts" Diligence Obligations in Life Science M&A, 18 The M&A Lawyer (June 2014); *e.g.*, *Himawan*, 2024 WL 1885560, at *11 (evaluating a merger agreement defining "commercially reasonable efforts" as "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [the buyer], with due regard to the nature of efforts and cost required for the undertaking at stake"); *Neurvana*, 2020 WL 949917, at *16-17 (dismissing a claim for breaching a commercially reasonable efforts provision that imposed an "outward facing definition" that applied "an industry-standard requirement . . . to define the diligence obligations of the buyer" where the complaint failed to identify comparators).

buyer's own diligence standards.[352] This is often more buyer friendly since the buyer can compare its past practices in similar situations to its present efforts.

As the Merger Agreement here demonstrates, however, these generalizations are subject to exception given the highly customized nature of earnout structures. J&J and Auris agreed to an inward facing provision to measure J&J's "commercially reasonable efforts" in advancing Auris's products. But Auris bargained for three crucial protections. First, J&J's efforts were to be in furtherance of "achiev[ing] each of the Regulatory Milestones"—not J&J's other corporate goals.[353] Second, J&J was required to devote efforts consistent with its "usual practice" for a "priority medical device."[354] This was doubly advantageous to Auris. Efforts to achieve the regulatory milestones must be at the high level J&J—a top company in the industry—set for itself, and for "priority" devices within J&J.[355] Third, J&J was

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[352] *See* Werling, *supra* note 351; *e.g.*, *FMLS Holding Co. v. Integris BioServices, LLC*, 2023 WL 7297238, at *7 (Del. Ch. Oct. 30, 2023) (considering a claim based on an inward-looking definition of commercially reasonable efforts, which looked to how the business was operating pre-merger); *Banas v. Volcano Corp.*, 47 F. Supp. 3d 941, 946 (N.D. Cal. 2014) (reviewing an inward facing "commercially reasonable efforts" clause requiring the buyer to use "efforts, sales terms, expertise and resources normally used by [Volcano] for other products, which, as compared with [products developed from the plaintiffs' assets]; are of similar market potential at a similar stage in its development or product life, taking into account all reasonable relevant factors affecting the cost, risk and timing of development and the total potential of the applicable [developed products], all as measured by the facts and circumstances at the time such efforts are due").

[353] Merger Agreement § 2.07(e)(i).

[354] *Id.* § 2.07(e)(ii).

[355] *See* DeFonzo Tr. 381-82 (recalling that Morano encouraged Auris to accept an inward facing standard by assuring it that J&J's standard exceeded industry standards); *id.* at 382-

prohibited from acting "based on taking into account the cost of making any Earnout Payment(s)."[356] This limitation is more restrictive than the typical requirement that a buyer not affirmatively act (or fail to act) for the purpose of thwarting an earnout payment.[357] The Merger Agreement also lacks language granting J&J complete discretion over decisions relating to Auris's business.[358]

With these assurances, Auris agreed to a deal with an earnout component.[359] That is, it forewent guaranteed cash in exchange for assurances that J&J would promote—not impair—its ability to reach the regulatory milestones. For J&J, this

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83 (discussing the choice of "priority medical device" language as a "residual assurance" that iPlatform would be prioritized within J&J). J&J put forth the expert opinion of Peter Hinchliffe on whether J&J's conduct was commercially reasonable. The Fortis expert he was rebutting—Dr. Paul Gompers—did not opine on this matter. To the extent that Hinchliffe offered any proper rebuttal testimony, much of it verged on legal opinions that I decline to accept. But even Hinchliffe acknowledged that the inward facing efforts standard in the Merger Agreement favored Auris. Hinchliffe Tr. 3145-46 (agreeing that the "inward-facing standard in the contract" favored Auris due to J&J's "high standards relative to the rest of the industry").

[356] Merger Agreement § 2.07(e)(iii).

[357] *See S'holder Rep. Servs. LLC v. Albertsons Cos.*, 2021 WL 2311455, at *1 (Del. Ch. June 7, 2021) (discussing a "typical" provision in which the buyer "bargained for the right to operate [the seller] post-closing in its discretion limited only by its express commitment not to operate [the seller] in a manner intended to avoid the obligation to pay the earnout"); *see also infra* note 391 (citing precedent).

[358] *See supra* note 346 and accompanying text (discussing precedent).

[359] *See* JX 278 at 6-7 (Luca Viarengo et al., *Enforcement Quality and the Use of Earnouts in M&A Transactions: International Evidence*, 45 J. Bus. Fin. & Acct., 437, 442-43 (2018) (observing that a seller may agree to an earnout clause if the contractual protections are "strong," making the seller "more confident that it will obtain what it is due").

meant that it paid less upfront but lost the ability to exercise unchecked discretion over the Auris products.

As discussed below, Auris's expectations went unmet. J&J did not devote commercially reasonable efforts to achieve the milestones consistent with those given to a priority device. Instead, it repeatedly impeded and impaired the development of Auris's products. J&J's efforts might have been beneficial to its broader robotics program, its profit margins, or its commercialization strategy. But they were wholly inconsistent with J&J's promises to Auris.

2. Whether J&J Breached the Efforts Provision

The Merger Agreement includes a bespoke "[e]fforts" clause.[360] Section 2.07(e)(i) imposes on J&J an affirmative obligation to use "commercially reasonable efforts" to advance the achievement of the iPlatform and Monarch regulatory milestones.

> From and after the Closing Date until the earlier to occur of the latest Earnout Period End Date with respect to the Regulatory Milestones or the date on which each of the Regulatory Milestones have been achieved in accordance with this Agreement, Parent shall, and shall cause its Affiliates (including the Surviving Corporation) to, use commercially reasonable efforts to achieve each of the Regulatory Milestones (excluding, once achieved, any such Regulatory Milestones that may have been achieved).[361]

[360] Merger Agreement § 2.07(e) ("Efforts; Certain Transfers").

[361] *Id.* § 2.07(e)(i).

The express requirement that J&J's objective be "to achieve each of the Regulatory Milestones" stands in stark contrast to J&J's understanding that it could "make whatever decisions needed to be made" about the Auris products "in the context of the rest of [J&J's] business."[362]

Delaware courts have interpreted "commercially reasonable efforts" clauses as requiring a party "to take all reasonable steps" toward an end.[363] Here, the parties bargained for a meaning. Section 2.07(e)(ii) of the Merger Agreement defines "commercially reasonable efforts" as:

> the expenditure of efforts and resources in connection with research and development and obtaining and furnishing of information to and communications with applicable Governmental Entities in connection with obtaining the applicable 510(k) premarket notification with respect to the applicable Robotics Products consistent with the usual practice of Parent and its Affiliates with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle to the applicable Robotics Products[.][364]

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[362] Morano Tr. 1532-34 ("[I]f we were spending $3.4 billion on [Auris], we were going to own the company, and we wanted and needed the right to be able to make whatever decisions needed to be made appropriately moving forward in the context of the rest of our business."); *e.g.*, JX 2339 (Martin to DeFonzo: "As a general note, we will manage the milestones to do what is the right for the business. They are meant to be collective incentives to drive the business in the right direction in service of maximizing value."); Martin Day 2 Dep. 564-65 (testifying that the goal was to "develop a system to delight the customers" because the "marketplace [] was waiting for a system from Johnson & Johnson"); *see also* JX 1663; JX 6206.

[363] *Williams Cos.*, 159 A.3d at 273; *see also Akorn*, 2018 WL 4719347, at *86-88; *Himawan v. Cephalon, Inc.*, 2018 WL 6822708, at *7 (Del. Ch. Dec. 28, 2018) (citation omitted).

[364] Merger Agreement § 2.07(e)(ii); *see also id.* § 10.03(eee) (defining "Robotics Products").

The definition goes on to list ten factors J&J may "take into account" in setting its level of efforts for a "priority medical device":

> (A) issues of efficacy and safety, (B) the risks inherent in the development and commercialization of such products, (C) the expected and actual competitiveness of alternative products sold or licensed by third parties in the marketplace, (D) the expected and actual patent and other proprietary position of the product, (E) the likelihood and difficulty of obtaining FDA and other regulatory approval given the nature of the product and the regulatory structure involved, (F) the regulatory status of the product and scope of any marketing approval, (G) pending or actual legal proceedings with respect to the applicable Robotics Product, (H) whether the product is subject to a clinical hold, recall or market withdrawal, (I) input from regulatory experts and any guidance or developments from the FDA or similar Governmental Entity, including as it may affect the data required to obtain premarket approval from the FDA or any similar approval from another Governmental Entity and (J) the expected and actual profitability and return on investment of the product, taking into consideration, among other factors, the expected and actual (1) third party costs and expenses, (2) royalty and other payments and (3) pricing and reimbursement relating to the product(s).[365]

Section 2.07(e)(iii) prohibits J&J from making decisions to avoid, or based on, the milestones:

> Parent shall not, and shall cause its Affiliates (including the Surviving Corporation) not to, take any actions, or refrain from taking any actions, concerning the business or operations of Parent or any of its Affiliates (including the Surviving Corporation) (A) with the intention of avoiding any of Parent's obligations to pay any Earnout Payment or (B) based on taking into account the cost of making any Earnout Payment(s) made,

[365] *Id.* § 2.07(e)(ii).

> or actually or potentially to be made, pursuant to this Agreement.[366]

Together, these provisions provide several layers of protection for Auris.

Although the ten factors J&J could consider in expending efforts and resources gave it some measure of discretion, the mandate that J&J follow its "usual practice" for "priority medical device[s]" cabined it.[367] The phrase "priority medical device" is undefined in the Merger Agreement. Based on its usual meaning, a "priority" device is one given "superiority in rank, position, or privilege."[368] J&J identified a single comparator "priority medical device at a similar stage in product lifecycle" to iPlatform and Monarch: an orthopedic RASD called Velys.[369]

Velys was developed through an MVP strategy starting with simple, buildable functionality and a single indication.[370] It lacked perfect performance statistics before receiving its first FDA clearance in January 2021 and was not superior (or

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[366] *Id.* § 2.07(e)(iii).

[367] *Id.* § 2.07(e)(ii).

[368] *Priority*, Merriam-Webster, https://www.merriam-webster.com/dictionary/priority (last visited Aug. 30, 2024); *Lorillard Tobacco Co. v. Am. Legacy Found.*, 903 A.2d 728, 738 (Del. 2006) ("Under well-settled case law, Delaware courts look to dictionaries for assistance in determining the plain meaning of terms which are not defined in a contract.").

[369] *See* Heda 30(b)(6) Dep. 29-32; PTO ¶ 164; *cf. Banas*, 47 F. Supp. 3d at 947 (applying Delaware law; discussing the importance of considering a relevant comparator device by which to measure commercially reasonable efforts where no adequate comparator was identified).

[370] *See* PTO ¶ 164; JX 4246 at 3; Waterson Dep. 98-99; Shen Tr. 1227-28.

even equivalent) to its market-leading rival upon launch in August 2021.[371] Velys employees were given cash incentives to achieve rapid FDA clearance.[372]

iPlatform received starkly different treatment than Velys. Instead of being prioritized, J&J subjected iPlatform to efforts that impaired its development and ability to secure planned clearances. J&J's efforts benefitted another device—Verb—at iPlatform's expense. It is obvious from the record that J&J's efforts toward the iPlatform regulatory milestones were not commercially reasonable, as defined in the Merger Agreement. J&J's breaches are, instead, reasonably certain to have caused iPlatform to miss its regulatory milestones.

I reach a different conclusion regarding Monarch. J&J diminished aspects of the Monarch program while prioritizing others. Fortis did not prove that these actions reflect a breach of J&J's efforts obligation.

a. Efforts Towards the iPlatform and GI Milestones

The Merger Agreement required J&J to use "commercially reasonable efforts," as defined in Section 2.07(e)(ii), to achieve the regulatory milestones.[373] Six regulatory milestones are tied to FDA clearance of iPlatform for increasingly

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[371] *See* Waterson Dep. 180-81; JX 3717; JX 3963; JX 4481 at 19-20; *see also* PTO ¶¶ 165-66.

[372] Waterson Dep. 103-106.

[373] Merger Agreement § 2.07(e)(ii); *see* Shen Tr. 1150-51 (confirming his understanding that J&J had an obligation to "exercise priority efforts to achieve the regulatory milestones in the merger agreement").

complex laparoscopic procedures.[374] A seventh—the GI Milestone—concerned clearance for an endoluminal procedure and could be satisfied with either iPlatform or Monarch.[375] J&J did not bestow on iPlatform the efforts and resources to achieve these milestones that would befit a "priority" device.[376]

Instead, J&J thrust iPlatform into a showdown with Verb. The fallout from Project Manhattan grew when the iPlatform robot and team were forced to merge with Verb. Compounding iPlatform's challenges, the iPlatform and GI regulatory milestones were deprioritized when they were written off and different incentives were imposed. This is the antithesis of the commercially reasonable efforts expected for a "priority" device.

i. *Project Manhattan*

Within weeks of closing, iPlatform was pitted against the Verb robot for the Project Manhattan competitive assessment.[377] To prevail, Auris had to prepare for a series of in-house surgical challenges rather than progress iPlatform's development. Auris's engineering team scrambled to gain functional system stability so that the fledgling iPlatform alpha robot could face the post-beta Verb—

[374] Merger Agreement § 2.07(a)(iii)-(vii).

[375] *Id.* § 2.07(a)(viii).

[376] *Id.* § 2.07(e)(ii).

[377] *See supra* Section I.L; *see also* JX 1702 ("Plan to Technically Assess Verb Platform and iPlatform").

taking on extensive "technical debt" in the process.[378] The legacy Auris team saw no alternative, since both iPlatform and Verb were "fighting for their lives."[379] Over 80 Auris personnel were diverted to "support a 25-day lab period."[380] Many of the Project Manhattan procedures assigned to iPlatform were more advanced than those Auris intended to use to satisfy Regulatory Milestones.

J&J insists that imposing Project Manhattan on iPlatform did not breach its efforts obligation because the exercise was meant to "identify synergies in order to accelerate the development of the robots."[381] But Project Manhattan had no upside for Auris. It did not advance iPlatform's development, provide it with resources, or bring it closer to regulatory approval. Quite the opposite.

For iPlatform, Project Manhattan caused needless setbacks and resource drains. To make matters worse, J&J delayed making resource decisions for Auris

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[378] *See* Mintz Tr. 589-91 (describing how the workarounds to prepare for Project Manhattan eliminated any "firm foundation" to fix problems in a "measured, controlled way" necessary for a complex robot and created problems to solve later); Moll Tr. 254 (explaining that Shen did not understand "all of the work that needed to be done just to get ready for any sort of technical assessment" and the "technical debt" Auris incurred "just to show up for this evaluation"); *see also* JX 4207.

[379] DeFonzo Tr. 406 ("[W]e were in a fight for our lives. . . . Verb us, and us Verb."); *see also* Moll Tr. 72 ("So we quickly characterized this as a bakeoff because the pitting of two systems against each other was – couldn't have been more different than the description of a technology audit that had nothing to do with Verb, that had everything to do with iPlatform and Monarch and how it could be – progress could be accelerated by resources from J&J.").

[380] JX 2389 at 9; *see also* JX 2444 at 8; JX 2330.

[381] Defs.' Answering Post-trial Br. 6 (emphasis removed).

until the assessment was complete.[382] For Verb, though, it was a boon. Through the assessment, J&J identified synergies between the robots so that iPlatform could optimize Verb.[383] Doing so gave J&J something to show the market and its Board for years of substantial investments in Verb while staying within the Ashley Management Decision budget. This result might be appropriate if I were considering whether J&J had used commercially reasonable efforts to develop Verb as a priority device. But J&J agreed to devote such efforts to iPlatform in pursuing the regulatory milestones. The iPlatform milestones were sacrificed to aid the Verb program.[384]

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[382] *See* JX 2103 ("July is a critical month with Manhattan project concluding. Auris's future needs to be assessed against the outcome of these strategic decisions."); Moll Tr. 86; *see also* JX 2403; JX 2019.

[383] *E.g.*, JX 6206 (Shen: "My original thought is to get Verb to market asap, and then iPlatform. Leverage as much as possible behind the scene. The overall consolidation of both platforms will take 5-10 years. The Tech Assessment will take us to the final decision."); Lenard Day 2 Dep. 23-24 ("If there are ways for us to take those two–and combine them to optimize what would eventually be our value–I never heard about [Project Manhattan] as a comparison between the two."). Lenard was J&J's Vice President of Finance for J&J's Robotics and Digital Solutions Group from 2019 until October 2022. Lenard Tr. 1785-1786.

[384] JX 1630 (Shen to McEvoy: "[i]Platform is exciting, but there is so much we do not know. Verb has challenges, but we already have a working prototype which can perform preclinical surgeries. Instrument is also developed. We need to be all in for Verb. Verb + iPlatform is our bullet proof strategy to compete."); *see also* JX 1820 (Shen: "The Tech Assessment is the No. 1 priority at this point for all of us."); JX 1703.

Project Manhattan alone is sufficient to find that J&J breached its efforts obligation in Section 2.07(e) of the Merger Agreement. A "priority" device would not have to endure a costly battle merely to remain operative.[385] But there is more.

ii. *The Verb Combination and Integration*

iPlatform's success in Project Manhattan came at a crippling cost. It led to the iPlatform system being meshed with Verb components, including certain hardware.[386] The complete integration of Verb into Auris followed.

Combining the RASDs hampered iPlatform's launch and milestone achievement.[387] Contemporaneous documents reflect that J&J knew pursuing the "[s]ingle, [o]ptimizied [p]latform" would negatively affect iPlatform's development schedule.[388] Worse, J&J anticipated that the delay would frustrate the iPlatform

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[385] Nothing of the sort was required of Velys. *See supra* notes 370-72 and accompanying text.

[386] JX 2594 at 20 (recommending "[g]o to market with Combination platform defined as 'iPlatform'+ (6-arm robotic architecture) augmented by incremental Verb capabilities incl. Open Console, Verily scope, Digital Assets at launch, followed by further iterations including UID integration").

[387] *See* Mintz Tr. 686 (discussing the difficulties faced by iPlatform's beta version due to "integration challenges"); *see also* Gardiner Tr. 822 (recounting that beta's software "crashed" when it was brought online).

[388] *See* JX 2566 at 10 (Sept. 2019 Manhattan Financials Update: "Single, Optimized Platform launching in 2024 (+1 Year Delay to Combine)"); McEvoy Tr. 2635 (acknowledging that combining the systems would mean a longer time to market for Auris); Lenard Tr. 1802-04; JX 2584 at 26 (draft investor presentation discussing "[l]onger time to market for Auris impacting retention" and "[m]ilestone [r]evisions for Auris employees" as considerations for combining Verb and iPlatform); *see also* JX 2554 at 23 (J&J Sept. 2019 deck suggesting two year delay for combination); JX 5122 at 19-20 (J&J employee texts expressing concern that a deck indicating delay from the combination could

regulatory milestones.[389] Gorsky endorsed the combined system after understanding that J&J had a "good overall value case" from a fair market value perspective considering "what [w]ould also happen with the contingent payment."[390] This was not only inconsistent with J&J's obligation to use commercially reasonable efforts to achieve the milestones. It was also contrary to J&J's promise not to act "based on taking into account the cost of making any Earnout Payment(s)."[391]

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be "used against us in litigation"); *compare* Dougherty Dep. 400-02, 404-05 (testifying that he was concerned Auris would learn about "scenario planning" to form a single platform), *with* Dougherty Tr. 3170-72 (attempting to walk back his deposition testimony).

[389] Unfortunately, Gorsky declined to attend trial and shed light on this exchange. Other potentially relevant evidence was lost because Gorsky failed to turn off auto-delete on his cell phone after receiving a litigation hold notice (in this and other litigation). Fortis moved for sanctions in October 2022. *See* Pl.'s Mot. to Compel Discovery and for Sanctions (Dkt. 214). I reserved judgment on the motion until trial. With the benefit of a full record, I conclude that Gorsky's failure to retain text messages is far from ideal, but it was neither reckless nor intentional. *See Seibold v. Camulos P'rs LP*, 2012 WL 4076182, at * (Del. Ch. Sept. 17, 2012) (explaining that "dispositive sanctions are "only appropriate where a party acts to intentionally or recklessly destroy evidence" (citation omitted)). Upon receiving the hold memo, Gorsky asked his assistant to ensure that he complied. Aff. of Alex Gorsky in Supp. of Defs.' Opp'n to Pl.'s Mot. to Compel Discovery and for Sanctions (Dkt. 226) Ex. A. This instruction shows an intention to comply. He also testified during his deposition that he had enabled auto-delete on his phone years ago and simply forgot. Gorsky Dep. 323-24. Gorsky was negligent. He did not, however, spoliate evidence.

[390] JX 2606 at 1-2 (Oct. 1, 2019 email from McEvoy to Gorsky, in response to his inquiry about why the combined system had a lower valuation); *see also* JX 2599 at 2 (CFO Pease explaining, before McEvoy emailed Gorsky, that the lower valuation was based on assuming that the iPlatform milestones were paid); McEvoy Tr. 2636-37 "Q: [T]he contingent payment you wrote about there included the milestones that you were contemplating writing down; correct? A: I presume so.").

[391] Merger Agreement § 2.07(e)(iii). This provision lacks an intent requirement. *Cf. Lazard Tech. P'rs, LLC v. Qinetiq N. Am. Operations LLC*, 114 A.3d 193, 194 (Del. 2015) (discussing a provision in a merger agreement prohibiting a buyer from "taking any action to divert or defer [revenue] with the intent of reducing or limiting the Earn-Out Payment"); *id.* at 195 (explaining that the Court of Chancery "properly held that [a] buyer's action had

The detrimental effects of the combination on iPlatform intensified when the entire Verb group was thrust upon Auris, which was trying to regain its footing after Project Manhattan.[392] In J&J's view, the integration is indicative of commercially reasonable efforts because Verb's resources were being devoted to iPlatform.[393] In reality, it was "highly disruptive," as J&J had predicted.[394] The Verb team, which had just learned it lost Project Manhattan, suddenly had to support a competitor robot. The iPlatform team went from nimble and focused to redundant and divided.[395] The "devastating" departure of the entire legacy iPlatform clinical

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to be motivated at least in part by [an] intention" to avoid an earnout and was not required to find that avoidance was the buyer's sole purpose).

[392] I do not necessarily view the integration as a separate breach. It was a continuation of the injury from Project Manhattan and the robot combination. iPlatform could no longer pursue its development and commercialization strategy. It, instead, had to battle, merge, and integrate with a competitor device.

[393] *See* Defs.' Answering Post-trial Br. 98-99.

[394] JX 2743 at 11 (J&J presentation describing the integration strategy as a "[o]ne time, highly-disruptive change"); *see* DeFonzo Tr. 425-27 (describing the integration as a "horrible experience" for both Auris and Verb since they had been "pitted against one another," which created a "toxic culture where, essentially, one program wins and the other program loses . . . [a]nd now, all of a sudden, it's, like, let's integrate these things"); JX 2921 at 1 (DeFonzo expressing his concern to J&J that the directive to "integrate as quickly as possible" is "unreasonable if we expect it not to disrupt development activities and core business unit objectives").

[395] *See* JX 3094 (J&J's Lenard: "After the Verb acquisition, I REALLY need to initiate layoffs – not just for my budget . . . but also for the good of the business. We have so many people now that we don't know what do to with everyone and it's slowing down our progress."); Mintz Tr. 613 ("Verb's software team at this point was almost twice the size. So now we have a situation where the team that sort of lost their baby was brought in to join this team, and they outnumbered them two to one. There's a dynamic there, even in the best of times."); *see also* JX 4495 ("Gompers Rep.") ¶ 69 (describing the importance of "firm-specific" human capital for entrepreneurial endeavors).

engineering team, and a number of Auris software engineers, resulted.[396] With Verb tethered to iPlatform, the swift pace Auris had once achieved was disrupted.[397]

J&J also argues that the combination and integration of Verb with iPlatform was a "commercially reasonable business decision[]" falling "well within J&J's discretion under the contract."[398] This reflects a fundamental misreading of the Merger Agreement. J&J could consider various factors in assessing the level of efforts to devote. But the end goal of those efforts was to achieve the iPlatform regulatory milestones—not to further J&J's robotics program.[399] A "priority" device would not have its system, technology, and team diluted to fix another device's problems.[400]

iii. *Thwarting of iPlatform's MVP Strategy*

The milestone structure that J&J and Auris agreed upon reflected an MVP strategy, albeit not explicitly. The first iPlatform regulatory milestone—the General Surgery Milestone—could be satisfied by any upper and any lower abdominal

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[396] *See* Mintz Tr. 612, 614-15 (explaining the "step back" to engineering and system stability caused by the integration and "significant" attrition that resulted); JX 3194.

[397] *See* JX 2991 at 4 (Feb. 2020 internal J&J presentation stating "[w]e can't underestimate the impact the 'non bake-off bake-off' has had on both companies"); Gompers Rep. ¶ 112 (opining that by "impos[ing] integration burdens on Auris management," J&J "impeded Auris' ability to achieve the Acquisition milestones").

[398] Defs.' Answering Post-trial Br. 103.

[399] Merger Agreement § 2.07(e)(i).

[400] Velys was never forcibly combined with another program. *See* Thomson Dep. 85-87; Waterson Dep. 328-39.

procedures.[401] From there, iPlatform would build towards more specialized procedures to achieve the 2023 umbrella and GI regulatory milestones J&J had allowed iPlatform to select.[402] The milestones proceeded iteratively from relatively simple to complex, without regard to architecture (e.g., number of arms used).[403]

At first, Auris considered pursuing either five-arm Nissen fundoplication or RYGB for the upper abdominal procedure and inguinal hernia repair for the lower abdominal procedure to satisfy the General Surgery Milestone.[404] Choosing RYGB for the upper indication was ambitious yet ideal, since Auris would have met two milestones at once (the General Surgery and Upper Abdominal Milestones).[405] But after Project Manhattan caused delay, Auris worried that RYGB was out of reach for 2021. It sought to simplify iPlatform's initial indications and features for regulatory approval purposes.[406]

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[401] Merger Agreement § 2.07(a)(iii).

[402] *Id.* § 2.07(a)(iv)-(viii); *see supra* note 186 and accompanying text; *supra* note 194.

[403] *See* Khan Tr. 3039-40.

[404] JX 1729 at 21-22; Mintz Tr. 691-93 (explaining that Moll initially preferred to work towards five-arm procedures); JX 824 at 29; *see supra* notes 74, 250, 270.

[405] Sheehy Dep. 110-11 (Auris clinical engineer testifying: "If we could get two milestones at the same time with the same set of activities, that would have been more efficient than sequentially going from milestone 1 to milestone 2."). Auris was confident at the time, based on its lab results, that iPlatform could perform RYGBs. *See infra* notes 541-43 and accompanying text.

[406] JX 2199 (Moll suggesting to Shen and Martin that iPlatform "go with [the] smallest and most efficient clinical effort to achieve desired regulatory clearances –> ie work to and only to FDA defined clinical activities" to "accelerate [its] momentum"); Moll Tr. 86-90; *see also* JX 6206.

Moll's requests to pursue an MVP version of iPlatform for its initial regulatory clearance, using simplified procedures that iPlatform was "very capable" of performing, were rebuffed by J&J.[407] J&J continued to insist that iPlatform focus on RYGB—a procedure that would promote Ethicon instrument sales and broad commercialization while putting achievement of the General Surgery Milestone in peril.[408] When Shen learned in May 2019 that Mintz planned to make "instrument trade-offs" to pursue 510(k) with a simplified indication, he asked a colleague to "intervene."[409]

J&J believes that the ten factors listed in the Merger Agreement's definition of commercially reasonable efforts allowed it to drive iPlatform towards the more complex procedure.[410] For example, "expected and actual profitability" would be furthered by an RYGB indication using high margin Ethicon instruments.[411]

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[407] Moll Tr. 88 ("RYGB is a more complex procedure. There are more questions with regard to port placement. There was more questions with regard to arm movement. We had lots of success in the lab with the single-quadrant procedures of gallbladders and Nissens and hernias and hysterectomies. We knew that we were very capable in those procedures."); *id.* at 89-91.

[408] *Id.* at 89-90.

[409] JX 6206 at 1 (Shen: "We cannot do the wrong things for the sake of [the] timeline."); *see also* JX 2172 at 1 (June 2019 email from Shen to Martin: "Another thing that bothers me is our milestone incentives. That may not drive the right behaviors."); Shen Tr. 1164-65.

[410] *E.g.*, Shen Tr. 1170-71 (stating that he believed the Auris team was too focused on the milestones as "opposed to a great product" with commercial viability); *see also* Defs.' Answering Post-trial Br. 44 ("Pursuing RYGB made commercial sense.").

[411] Merger Agreement § 2.07(e)(ii)(J); *see* Moll Tr. 89-91.

iPlatform's "expected and actual competitiveness" versus da Vinci could also improve using a five or six-arm architecture.[412] Still, J&J's insistence that iPlatform's foray into regulatory approval involve a complex five-arm procedure impeded the achievement of the 2021 milestone. It did not provide "efforts and resources . . . in connection with obtaining the applicable 510(k) premarket notification . . . consistent with the usual practice of [J&J] with respect to [a] priority medical device."[413]

Although J&J was entitled to consider certain factors in devoting efforts and resources to iPlatform, its discretion was not free floating. J&J was not, for example, permitted to prioritize commercialization, product differentiation, or short-term profitability at the expense of achieving the milestones.

Even if it could, those considerations were promoted through an MVP approach for regulatory approval. Auris proved that:

- "[I]ssues of efficacy and safety" counsel in favor of starting with a basic device and simple procedures before adding complexity in later iterations.[414]

[412] Merger Agreement § 2.07(e)(ii)(C).

[413] *Id.* § 2.07(e)(ii).

[414] *Id.* § 2.07(e)(ii)(A); *see* Shen Tr. 1168-69; Moll Tr. 16.

- "[T]he risks inherent in [] development" are lower with an MVP strategy. It simplifies the system to ensure speed, flexibility, and reliability, which reduces development risk.[415]

- "[T]he likelihood and difficulty of obtaining FDA and other regulatory approval" favors starting with a narrow indication before seeking to expand the device's approval.[416]

- Commercial considerations—including "profitability and return on investment," the "competitiveness of alternative products," and the "risks inherent in . . . commercialization"—support an MVP strategy.[417] An MVP approach would have allowed J&J to assess the valuable aspects of iPlatform before investing in the development of a fully featured product.[418] Even a minimally viable version of iPlatform using fewer arms would have "plenty of differentiation" from da Vinci to drive adoption.[419]

Numerous witnesses at trial confirmed that it is industry standard to follow an MVP strategy for the development and regulatory approval of complex medical

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[415] Merger Agreement § 2.07(e)(ii)(B); *see* Khan Tr. 3042 (J&J's technical expert confirming that an MVP strategy promotes system speed, flexibility, and reliability); *see also* Khan Day 1 Dep. 214 ("The simpler the system at the initial stages, the easier it is to ensure system stability and solve other problems."); Grennan Dep. 112-14 (J&J's rebuttal economics expert testifying about MVP); Gompers Rep. ¶ 62 ("[T]he MVP approach accelerates time to market relative to the product-development model used by established companies to enter known markets.").

[416] Merger Agreement § 2.07(e)(ii)(E); *see* Tillman Tr. 2825-27 (J&J's regulatory expert acknowledging that it is a common regulatory practice to seek clearance of an early device with limited functionality, which can be a predicate for future iterations); *accord* Wittwer Tr. 1959; *see also* Shen Tr. 1166-67; Moll Tr. 293-94; Khan Day 1 Dep. 209.

[417] Merger Agreement § 2.07(e)(ii)(B), (C), (J); *see* Gompers Tr. 1935-36; Grennan Dep. 112-14.

[418] *E.g.*, Shen Tr. 1169; Grennan Tr. 2545; Gompers Tr. 1916-18, 1935-36; Khan Tr. 3041-42; Lopes Tr. 2444.

[419] Moll Tr. 90; *id.* at 294-95; *see also* Shen Tr. 1167; Grennan Dep. 58.

devices.[420] For RASDs in particular, the approach is highly efficient.[421] In terms of priority devices, J&J's own practice for Velys was to follow an MVP strategy.[422] Gorsky also had asked that an MVP approach be used for Verb.[423] Thus, J&J's insistence that iPlatform focus on a complex umbrella procedure to satisfy the General Surgery Milestone was not commercially reasonable in view of J&J's obligation to devote efforts befitting a priority medical device.

iv. *The New Incentives*

In April 2020, J&J wrote down the iPlatform and GI regulatory milestones to $0.[424] This was an accounting measure; it did not eliminate J&J's contractual obligation to fund earnout payments if Auris timely met milestones.[425] But the write-

[420] *See* Shen Tr. 1164, 1169; Khan Tr. 3041-42; Khan Day 1 Dep. 207, 209; Moll Tr. 15-16.

[421] *See supra* notes 19-22 and accompanying text.

[422] *See* JX 4246 at 3 ("As part of the deal model, it was agreed that we would do a true MVP with the objective to enter the US market as quickly as possible."); Waterson Dep. 98-99; Shen Tr. 1227-28.

[423] *See* JX 255 at 1 ("Alex has asked us to . . . make sure we hit the goals and deliver the first general 'minimally viable product'"); JX 711 at 3 (targeting "1 indication" for a "[r]educed program scope" to accelerate launch); Shen Tr. 1167.

[424] JX 3139 at 2; PTO ¶ 161.

[425] Defs.' Answering Post-trial Br. 111-12.

down was accompanied by an employee incentive program with targets different from the milestones in the Merger Agreement.[426]

In contrast to the General Surgery Milestone that Auris had bargained for, the new regulatory approval incentive was based on FDA approval of iPlatform for a "general surgery" indication (like RYGB).[427] The program set a target date for iPlatform's initial FDA approval at the end of 2023—two years later than the deadline in the Merger Agreement.[428] All other regulatory milestones for iPlatform and GI-related incentives were absent from the program.[429]

These different inducements, coupled with J&J's communications to Auris that the milestones were "canceled,"[430] negatively affected employees' motivation to work towards the iPlatform and GI regulatory milestones in the Merger Agreement.[431] J&J was not using "commercially reasonable efforts" toward meeting

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[426] JX 2675 at 1 (discussing, in October 2021, the potential need to "construct an employee specific plan to 'restore' milestone achievability through creating a new separate retention program"); Moll Tr. 95-97; Mintz Tr. 617-18.

[427] *Compare* JX 3641 at 5, *with* Merger Agreement § 2.07(a)(iii); *see also supra* note 193 and accompanying text.

[428] *Compare* JX 3641 at 5, *with* Merger Agreement § 2.07(a)(iii).

[429] *Compare* JX 3641 at 5, *with* Merger Agreement § 2.07(a)(iv)-(viii). It also replaced gross revenue-based sales milestones with incentives based on profitability and overseas expansion. *Compare* JX 3641 at 5, *with* Merger Agreement §§ 2.07(a)(ix)-(x).

[430] *See* Moll Tr. 95-96, 195, 198; *see also* JX 3193.

[431] *See* Gompers Rep. ¶ 117.

the regulatory milestones "consistent with [J&J]'s usual practice" for a "priority" device.[432] It was redirecting efforts toward different goals.

This is not to say that J&J had to pursue the milestones without any regard to commercial reasonableness. But though J&J could reasonably calibrate its efforts, it could not try to re-write or deprioritize the milestones themselves. Velys never received similar treatment.[433]

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J&J was required to utilize commercially reasonable efforts to meet the iPlatform and GI regulatory milestones, consistent with those given to a priority medical device. Its actions beginning with Project Manhattan were anything but. A priority device benefitting from such efforts by J&J would not be embattled, derailed, and enmeshed with another. Velys was not.

Regardless, J&J insists that the efforts devoted to iPlatform were commercially reasonable because iPlatform's funding vastly exceed that of Velys (or any other medical device program at J&J).[434] J&J invested over $2.25 billion in the Auris program (broadly speaking) from 2019 to 2022.[435] It also purchased a

[432] Merger Agreement § 2.07(e)(ii).

[433] *See supra* notes 370-72 and accompanying text.

[434] Defs.' Answering Post-trial Br. 102. J&J makes similar arguments about staffing, which fail for the same reasons as its financing arguments and those discussed above regarding the post-integration debacle.

[435] *See* JX 4516 ("Malackowski Rep.") 283-84; Defs.' Answering Post-trial Br. 102.

company called Vytronus for $20 million to buttress Auris's capabilities, at Moll's request.[436]

It is an oversimplification to view these funds as furthering the achievement of the iPlatform regulatory milestones. For example, $112 million of the funds J&J claims were for iPlatform were spent on the Verb robot and instrument R&D, $89 million was spent on Ethicon legal fees (including this litigation), and $90 million was spent to acquire the remaining interest in Verb.[437] Much of the investment came post-write-down, and one-third of the cited total was spent after J&J abandoned iPlatform in 2022.[438] An obligation to use commercially reasonable efforts in pursuit of the iPlatform regulatory milestones is not equivalent to spending large sums on J&J's robotics program. J&J fell short of the promise it made in Section 2.07(e) of the Merger Agreement.

b. J&J Efforts Towards the Monarch Milestones

The Merger Agreement includes two regulatory milestones for Monarch: one focused on soft tissue ablation and the other on endourology. J&J's contractual

[436] JX 2825 at 1; Martin Tr. 1767-68; Leparmentier Dep. 210-12.

[437] *See* Malackowski Rep. 283-84; *see also* Defs.' Trial Demonstrative ("Defs.' Dem.") 10. Other expenditures included $214 million for additional instruments R&D, $60 million for marketing products other than iPlatform and Monarch, and $75 million for standalone "Digital Solutions" software products. *See* Malackowski Rep. 283-84; Kilroy Dep. 263-64; *see also* Defs.' Dem. 10.

[438] *See* Malackowski Rep. 283-84; *see also* Defs.' Dem. 10.

obligations extended to these milestones.[439] Fortis contends that J&J failed to use commercially reasonable efforts to achieve them.

Monarch's story is distinct from iPlatform's. Monarch was not subjected to Project Manhattan. Its system was not joined with another robot. It was largely permitted to follow an MVP strategy. And its regulatory milestones were not written down until September 2020.[440]

Fortis's arguments regarding the Monarch milestones are, at bottom, disagreements with how J&J engaged with the FDA and prioritized aspects of the Monarch program. Funding was allocated towards some Monarch indications instead of others, there were hiring gaps, and J&J's actions towards solving the NeuWave FLEX problem were bungled. These actions, or lack thereof, were flawed and may prompted unintended delays, but they are not commercially unreasonable under Section 2.07(e).

i. *Soft Tissue Ablation*

The Monarch Soft Tissue Ablation Milestone contemplated 510(k) approval for a "specific indication for robotically driven (or controlled) soft tissue ablation,"

[439] Merger Agreement § 2.07(e)(i); *id.* § 10.03(zz) (defining "Regulatory Milestones" to include "the Monarch Endourology Milestone" and the "Monarch Soft Tissue Ablation Milestone").

[440] JX 3504 at 3. The new employee incentive plan did, however, prioritize reusable bronchoscopes rather than the Soft Tissue Ablation Milestone and lacked any endourology incentives. *See* JX 3641 at 5.

including "instruments and accessories required to perform such ablation" by the end of 2022.[441] To meet the milestone, Monarch would need to use the NeuWave FLEX catheter.[442] But FLEX was in regulatory limbo after the patient death during its lung tissue study.[443] A "microwave pole" being developed by another company, which could have replaced FLEX to perform the ablation procedure, became unavailable after its developer was acquired.[444]

Fortis argues that J&J's efforts obligation required it to promptly conduct a new clinical study on FLEX.[445] It disagrees with J&J's initial strategy of advocating to the FDA that an IDE was unnecessary.[446] Fortis—with the benefit of hindsight—may be correct that J&J's strategy flopped. That does not mean, however, that J&J's attempts were commercially unreasonable in real time.

J&J engaged in multiple discussions with the FDA to find the shortest path to regulatory clearance for FLEX, consistent with the Soft Tissue Ablation Milestone.[447] That the FDA continued to insist J&J conduct clinical trials and seek

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[441] Merger Agreement § 2.07(a)(ii).

[442] Moll Tr. 51.

[443] *See supra* notes 172-74 and accompanying text.

[444] Leparmentier Tr. 995.

[445] Pl.'s Opening Post-trial Br. 122 (citing Wittwer Tr. 1968-69).

[446] *Id.* at 80 (arguing that "J&J squandered a meeting with the FDA"); *see* JX 2313 at 8-10; JX 2648 at 35-36.

[447] *See* Bryant Tr. 2500-01.

an IDE for FLEX related to lung tissue ablation is no fault of J&J. In 2020, at the FDA's encouragement, J&J obtained a Breakthrough Device Designation for FLEX.[448] The Breakthrough Device Program is a priority FDA program for devices offering a public health benefit with "significant regulatory advantages."[449] By the end of 2020, the FLEX team made several regulatory submissions, held multiple meetings with the FDA, and completed pre-clinical animal studies.[450] As a result of those efforts, in November 2021, the FDA conditionally approved an IDE for FLEX in lung treatment.[451] Despite that, the remaining clinical data and regulatory submissions for final approval meant that Monarch could not meet the 2022 milestone.

Setting aside whether J&J should have told Auris about the patient death sooner,[452] J&J's efforts were commercially reasonable. The delay caused by the patient death and the resulting requirements imposed by the FDA were not in J&J's control. Although Velys never faced a similar regulatory hurdle, J&J's iterative and consistent engagement with the FDA for Monarch reflects the sort of efforts one

[448] JX 3294; *see also* JX 2313 at 10.

[449] Tillman Rep. ¶ 29.

[450] *See* JX 3657 at 11.

[451] *See* Tillman Rep. ¶ 288.

[452] As discussed below, Auris is entitled to recover for this milestone due to fraud. *See infra* Section II.B.4.

would expect it to undertake for a priority device. In setting the level of its efforts, J&J was entitled to consider "the regulatory status of the product and scope of any marketing approval, . . . whether the product is subject to a clinical hold, recall or market withdrawal, [and] input from regulatory experts and any guidance or developments from the FDA."[453] Had J&J succeeded in persuading the FDA that an IDE was not needed for FLEX, it would have saved time for Monarch to meet the Soft Tissue Ablation Milestone.

ii. *Endourology*

The Endourology Milestone required Monarch to obtain 510(k) approval "for endourology procedure(s)" by the end of 2020.[454] Auris had solved major scientific problems with the procedure and planned to satisfy the milestone with an MVP approach.[455] Fortis argues that J&J failed to provide adequate resources to do so.[456] Instead, to address a "known budget gap" in 2020, J&J decided that the "[p]rimary Monarch focus" would be bronchoscopy rather than endourology.[457]

[453] Merger Agreement § 2.07(e)(ii)(F), (H)-(I).

[454] *Id.* § 2.07(a)(i).

[455] Leparmentier Tr. 983-84, 1017-18.

[456] Pl.'s Opening Post-trial Br. 81.

[457] JX 3091 at 3.

Velys received requested funding, space, and personnel.[458] By comparison, endourology was 15% understaffed and partially underfunded.[459] But even if Monarch's endourology team had proportionately less resources than Velys, it is not apparent that J&J's efforts deviated from its usual practice in supporting research, development, and regulatory interactions for a priority device. J&J logically prioritized a staged approach to Monarch's development.

Monarch Uro's planned 510(k) submission depended upon the to-be-approved Monarch Bronch 2.0 three-arm cart first receiving 510(k) clearance.[460] Monarch could not seek approval for Uro until after Bronch 2.0 obtained it in April 2020.[461] J&J's efforts and resources in furtherance of bronchoscopy necessarily advanced Monarch's chance of achieving the Endourology Milestone. The Merger Agreement permitted J&J to consider "the likelihood and difficulty of obtaining FDA and other regulatory approval" in setting the level of its efforts, which would reasonably include focusing on an indication necessary for a subsequent clearance.[462]

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[458] *See* JX 356; Thomson Dep. 55; Waterson Dep. 130-31, 341.

[459] *See* Leparmentier Tr. 1019-21; JX 3195; JX 3091 at 3.

[460] *See* JX 975 at 4 (communicating this plan to the FDA); *see also* JX 637 at 9-12; JX 673 at 5. Bronch 1.0, which already had 510(k) clearance, only had two arms. Monarch Uro required the Bronch 2.0 three-arm version to be cleared.

[461] Tillman Rep. ¶¶ 223-25.

[462] Merger Agreement § 2.07(e)(ii)(E).

3. Whether Fortis Was Damaged

Fortis must next prove with "reasonable certainty" that J&J's breaches of the Merger Agreement caused it injury.[463] Fortis contends that J&J's failure to use commercially reasonable efforts prevented Auris from achieving the iPlatform regulatory, GI, and net sales milestones.[464] J&J, for its part, asserts that Fortis cannot prove that its injury "flowed from [J&J's] violation of the contract" rather than "other intervening causes."[465] I consider these arguments for iPlatform milestone by milestone.[466]

a. iPlatform Regulatory Milestones

The Merger Agreement outlines six regulatory milestones for iPlatform: the General Surgery Milestone, four umbrella procedure milestones (the Upper Abdominal Milestone, the Lower Abdominal Milestone, the Urologic Milestone,

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[463] *Siga Techs., Inc. v. PharmAthene, Inc.* ("*Siga II*"), 132 A.3d 1108, 1111 (Del. 2015) ("[W]hen a contract is breached, expectation damages can be established as long as the plaintiff can prove the fact of damages with reasonable certainty." (emphasis removed)); *see also Cura Fin. Servs. N.V. v. Elec. Payment Exch., Inc.*, 2001 WL 1334188, at *19-20 (Del. Ch. Oct. 22, 2001) ("[R]easonable certainty is not equivalent to absolute certainty; rather, the requirement that plaintiff show defendant's breach to be the cause of his injury with 'reasonable certainty' merely means that the fact of damages must be taken out of the realm of speculation." (quoting *Tanner v. Exxon Corp.*, 1981 WL 191389 (Del. Super. July 23, 1981))).

[464] *See* Pl.'s Opening Post-trial Br. 121-26.

[465] Defs.' Answering Post-trial Br. 112 (quoting *LaPoint*, 2007 WL 2565709, at *9).

[466] Because Fortis did not prove a breach of contract as to J&J's Monarch-focused efforts, I do not consider whether Fortis suffered damages related to Monarch.

and the Gynecologic Milestone), and the GI Milestone.[467] Pre-merger, J&J estimated an 85% probability of meeting the General Surgery Milestone and an 75% probability of meeting the umbrella and GI milestones.[468] J&J insists that its predictions were misguided for two overarching reasons: technical issues and regulatory challenges.[469]

On the technical front, J&J points to evidence of "problems with workspace, thermal issues, system stability, emergency patient access, and instrument performance."[470] To be sure, these were challenges that the iPlatform team would need to solve. J&J obstructed Auris's ability to do so by imposing Project Manhattan shortly after closing, and then combining iPlatform with Verb.

Beyond that, I view J&J's insistence that technical deficiencies led to the failed milestones with skepticism. J&J engaged in multiple rounds of due diligence, involving experienced Verb engineers and outside robotics experts at Sagentia.[471] J&J gained direct insight through its Auris board observer seat.[472] J&J knew about iPlatform's strengths and weaknesses before projecting that the milestones would

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[467] Merger Agreement § 2.07(a)(iii)-(viii).

[468] JX 3139.

[469] Defs.' Answering Post-trial Br. 112-13.

[470] *Id.*

[471] *E.g.*, JX 447; JX 1076; Mintz Tr. 575-78; *see also* DeFonzo Tr. 354-57.

[472] *See* PTO ¶ 107; Morano Tr. 1445-47; Mintz Tr. 575-78; McEwen Dep. 71; *supra* note 103 and accompanying text.

likely be achieved and acquiring Auris.[473] When J&J wrote down the milestones in April 2020, it cited the FDA pathway change to De Novo—not technical issues—as the basis.[474]

It was only after Fortis sued in October 2020 that J&J began searching for diligence files suggesting technical flaws in iPlatform's system.[475] This appears to be tactical backfilling.[476] One frequently cited example is Auris's selection of the Silverton-style arm for iPlatform rather than the redesigned Superton arm, which J&J calls a hasty choice detrimental to iPlatform's success that was hidden from J&J.[477] As Mintz explained, though, iPlatform's choice was neither rash nor

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[473] *E.g.*, JX 1284.

[474] JX 3139 at 2; *see* Lenard Tr. 1830.

[475] JX 3814 (Shen telling Joachim to be "THE leader to own the [Auris acquisition] narrative"); *see supra* notes 319-21 and accompanying text.

[476] For instance, J&J argues that "DeFonzo provided J&J with a version of the iPlatform team's January 2019 quarterly program review that had been doctored to remove references to significant problems with workspace, thermal issues, and instrument performance" and that "Auris similarly altered other technical materials shared with J&J." Defs.' Answering Post-trial Br. 41. The internal version and external version are of the quarterly update are different. *Compare* JX 1130, *with* JX 1113 at 8, 29-34, 35, 37. But there is no credible evidence suggesting that Auris set out to hoodwink J&J or "doctor" documents. Instead, Auris's internal documents were simply cleaned up and revised before being sent to a potential outside investor/acquiror. *See* DeFonzo Tr. 510-14.

[477] Defs.' Post-trial Answering Br. 62; *see* Defs.' Dem. 22 at 53-60. J&J relied on the expert opinion of Dr. Moiz Khan to support its argument that iPlatform's design and system suffered from fatal flaws. Khan's critiques of iPlatform were based on his review of a subset of documents and videos. He never operated the robot and saw the robot just once in passing. Khan Tr. 2971-73. Because of his limited exposure to the robot, I give his testimony about specific challenges facing iPlatform little weight.

nefarious; it was strategic and evident.[478] Nevertheless, I weigh specific arguments in the context of each milestone despite my overarching cynicism that technical problems are to blame for the missed milestones.

On the regulatory front, the primary matter raised by J&J is the FDA's pivot from the 510(k) to the De Novo pathway for RASDs. This change, in J&J's estimation, "doomed any hope of meeting the milestones."[479] The milestone most directly affected by the pathway change is the General Surgery Milestone. If iPlatform had timely obtained De Novo approval for one upper and one lower abdominal surgical procedure, it could follow the 510(k) pathway for the subsequent regulatory milestones.[480] As such, I mainly consider the effects of the FDA's

[478] Mintz Tr. 718 ("So this balance of reach, access, stiffness, bandwidth, you have to get all of those right. And having gotten the stiffness and bandwidth we did in a long, skinny arm was not something to give up lightly. And we were completing procedures."); *id.* at 711 ("None of these risks were hidden."). Mintz was a compelling witness. He had extensive experience developing successful RASDs, including at Intuitive. He was vital to iPlatform's development and has unmatched knowledge of the design and development process from its infancy in 2016 through the selection of the beta design in early 2021. *Id.* at 711-12. Mintz testified candidly about iPlatform's technical challenges and what it took to solve them. *See, e.g.*, *id.* at 619-22. Despite Mintz's passion for the iPlatform system and his financial incentives, his testimony was highly credible relative to that of Khan. .

[479] Defs.' Answering Post-trial Br. 111.

[480] *See* Wittwer Rep. ¶ 22 ("If iPlatform had obtained De Novo approval for its general surgery application, J&J could have used iPlatform itself as a predicate device allowing use of the 510(k) pathway for pre-market clearance of further indications contemplated under subsequent 'umbrella' regulatory milestones for iPlatform. This would have reduced the regulatory approval timelines for these later applications."); *see also* Wittwer Tr. 1959.

position change in the context of the General Surgery Milestone. It is with that milestone that I begin.

i. *General Surgery Milestone*

The General Surgery Milestone required iPlatform to receive 510(k) clearance "for one upper abdominal surgical procedure" and "one lower abdominal surgical procedure" by the end of 2021.[481] iPlatform was on track to meet this milestone at the time of the merger. Before closing, iPlatform's pre-alpha prototype had completed procedures that would have satisfied it.[482]

iPlatform's program timeline gave it five months to secure an initial 510(k) approval.[483] This was "ambitious."[484] To reduce risk, Auris built in a "healthy" buffer of five additional months, ending on the last day of 2021.[485] Based on iPlatform's progress and optionality over which upper and lower clinical indications to pursue, the Auris team believed that the iPlatform General Surgery Milestone would likely be met.[486]

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[481] Merger Agreement § 2.07(a)(iii).

[482] *See* JX 5012 at 1; JX 699 at 9; JX 2610; Mintz Tr. 579-80; Gardiner Tr. 743-51.

[483] JX 1689 at 13-14; Mintz Tr. 579-80.

[484] DeFonzo Tr. 505-06.

[485] *Id.*; *see also* Mintz Tr. 659-60 (explaining that the timelines reflected "when we could reasonably, aggressively expect things to go" plus a buffer).

[486] JX 1413 at 2 (estimating a 65% probability of success for the first milestone); Mintz Tr. 580.

The record supports Auris's assessment. After the merger, iPlatform continued to receive high marks from surgeons.[487] It performed well in Project Manhattan.[488] It went on to successfully complete 40 cadaver labs from mid-2019 to early 2020 in which all milestone procedures were performed—including the most complex LAR and RYGB procedures.[489] The labs were, at times, imperfect and some physicians disliked the iPlatform system.[490] But regulatory approval is measured by clinical safety and effectiveness—not commercial readiness.[491] It is

[487] *See generally* Pl.'s Dem. 13 (lab results).

[488] *See supra* notes 252-56 and accompanying text; *see* Wittwer Tr. 1957 (testifying that, in her opinion as a regulatory expert, iPlatform's results in Project Manhattan would be "sufficient to . . . proceed to the next stages of product development for certain procedures").

[489] Pl.'s Dem. 13, lines 12-51 (showing that iPlatform completed cadaver lab procedures including 14 LARS, 10 RYGBs, 6 ventral hernias, 1 inguinal hernia, 2 partial nephrectomies, and 1 hysterectomy); Gardiner Tr. 752-53, 772, 800-03. Gardiner completed over 30,000 surgeries in his decades-spanning career, with about 30% being performed with a RASD. *Id.* at 722-23. He also instructed other surgeons on how to perform robotic surgeries and worked with Moll at Intuitive in developing the da Vinci robot. *Id.* at 724. Despite his financial incentives as an Auris stockholder, his testimony was highly credible.

[490] *E.g.*, JX 699 at 37; JX 3047; JX 3550. iPlatform was not for everyone. Hagen, one of the Project Manhattan KOPs involved with developing Verb, strongly disliked the architecture of iPlatform. She preferred a live assistant rather than the fifth robotic arm. Gardiner Tr. 768-71; Hagen Tr. 2344-45.

[491] *See* Wittwer Rep. ¶ 179 ("Medical devices do not need to be fully ready to enter large-scale commercial distribution before a company seeks regulatory clearance for them."); Wittwer Tr. 1954; Grennan Tr. 2547 (acknowledging the difference between regulatory maturity and commercial readiness for a complex medical device); *see also* Gardiner Tr. 726-28.

often desirable to obtain regulatory clearance for a prototype without the full functionality of a planned commercial device.[492]

In September 2021, J&J acknowledged that iPlatform would be capable of the Nissen fundoplication procedure that would satisfy an upper abdominal surgery indication.[493] For the lower abdominal indication, inguinal hernia labs from 2019 through 2020 show iPlatform's capacity to successfully perform the procedure.[494] Surgeons performing those labs rated iPlatform's performance as "superior to" or "competitive with" da Vinci."[495] In September of 2021, J&J again acknowledged that iPlatform would be capable of inguinal hernia and appendectomy—both lower abdominal procedures that would satisfy the first milestone.[496] If the results were replicated through the verification and validation phases, there would be sufficient

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[492] *See* Wittwer Tr. 1955-56 ("[I]t's actually desirable to submit your first application with fewer features and focusing on a select procedure or two to obtain that first De Novo clearance."); Wittwer Rep. ¶¶ 179-81. Auris's ARES robot is one such example. *See* Leparmentier Tr. 977 (explaining that ARES received FDA clearance using an MVP strategy and was never intended to be commercially launched); Moll Tr. 293-94.

[493] JX 4129 at 27 ("Based on experience with primary procedures, system should [] be capable of: . . . Nissen Fundoplication"). As discussed above, Auris initially considered pursuing either Nissen fundoplication or RYGB for its first upper abdominal procedure. *See supra* note 404 and accompanying text; JX 1729 at 21-22.

[494] *See* Pl.'s Dem. 13; JX 1541.

[495] JX 2622 at 15 (four 2019 iPlatform inguinal hernia labs completed with "high confidence" with ratings of "[b]est in class" and "superior to Da Vinci"); JX 3610 at 2 (Gardiner in 2020 reporting to Joachim that iPlatform's inguinal hernia procedure was "largely cooked" and "already competitive to the predicate").

[496] JX 4129 at 16 ("Beta will be capable in Inguinal Hernia[.]"); *id.* at 17 ("Beta system should be capable based on experience with primary procedure(s): Appendectomy[.]").

data for the FDA to assess iPlatform's safety and effectiveness for the proposed indication.[497] iPlatform could obtain approval for a single successful procedure.[498]

Overall, the record supports a finding that iPlatform would likely have met the General Surgery Milestone had J&J fulfilled its promises to Auris. iPlatform was on track to achieve the milestone before Project Manhattan and the Verb integration. J&J's insistence that iPlatform pursue a five-arm RYGB, instead of simpler procedures using a minimally viable device, made matters worse. J&J's adoption of new employee incentives in 2020 that conditioned the first payment on achieving a complex general surgery indication further re-directed resources away from the General Surgery Milestone. It is reasonably certain that J&J's breach of its efforts obligation (and, as discussed below, an implied term regarding the De Novo pathway) damaged Auris by preventing it from timely securing regulatory approval.

Technical Problems. J&J contends that, regardless of its conduct, iPlatform could never have met the General Surgery Milestone because of "fundamental technical challenges" with the system's workspace.[499] Workspace relates to the architecture of the robot, such as whether the arms experience collisions during procedures.[500] The record provides little support for J&J's assertion. Although

[497] Wittwer Tr. 1958.

[498] *Id.* at 1959.

[499] Defs.' Post-trial Answering Br. 59.

[500] Moll Tr. 270-71.

workspace issues arose, numerous lab reports show that iPlatform had the capability to safely and effectively complete procedures to satisfy the milestone.[501]

The other technical issues J&J cites were "surmountable."[502] They were similar to ones Auris leadership had tackled at Intuitive 20 years earlier.[503] Thermal issues made the robot hot to the touch.[504] iPlatform's system was sometimes unstable.[505] And a worst-case scenario persisted since the robot's arm setup meant that a very large patient could not be transported from the operating table to a gurney if a hospital lost power mid-procedure.[506] Such engineering challenges are expected while developing a highly complex medical device.[507]

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[501] *E.g.*, Pl.'s Dem. 13; JX 3685 at 7 (reporting "[a]dequate approach and workspace for 4-arm RYGB to move forward with US IDE" as of November 2020); JX 4129 at 15-19 (stating that iPlatform would be "capable" in Nissen fundoplication, inguinal hernia, small ventral hernia, appendectomy, prostatectomy, and hysterectomy, among other procedures); *see also* Khan Tr. 3004 (testifying that "capable" means safe, effective, and able to complete the procedure).

[502] Kilroy Tr. 2136-37 ("Other engineering challenges, I saw them as more surmountable . . . [T]he real showstoppers for the system were workspace and collisions."); Khan Day 1 Dep. 543 ("I didn't state many issues being fundamental and existential. I only said that to the workspace . . . .").

[503] Mintz Tr. 561.

[504] This was known to J&J during diligence. *See* JX 1284 at 12; Mintz Tr. 716 (Mintz recalling J&J's engineer touching an iPlatform arm during diligence and commenting on the temperature).

[505] Mintz Tr. 572-73.

[506] Joachim Tr. 2233, 2236-38. J&J cites iPlatform's poor instrument performance as another flaw. As Joachim admitted, however, instrument performance would not prevent iPlatform from meeting regulatory milestones. *Id.* at 2173-77.

[507] Mintz Tr. 572-73.

Many of these issues would not inhibit straightforward procedures that could satisfy the General Surgery Milestone, such as Nissen fundoplication and inguinal hernia, which the pre-alpha robot had successfully performed. Advanced capabilities, like using five or six arms, were not necessary to perform these procedures safety and effectively for regulatory purposes.[508] Despite that, the iPlatform team had been working to address various technical problems.[509] It was derailed when iPlatform was forced to participate in Project Manhattan and then combine with a separate system. These complications—all imposed by J&J—not only delayed iPlatform's progress but also imposed months of technical debt and unanticipated roadblocks.

Regulatory Problems. J&J also argues that the iPlatform General Surgery Milestone was unmet due to the FDA's pathway change. The General Surgery Milestone (like all iPlatform regulatory milestones) required iPlatform to obtain "510(k) clearance."[510] But in August 2019, the FDA said that the 510(k) pathway was unavailable to RASDs.[511] iPlatform unexpectedly had to follow the De Novo pathway.

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[508] *Id.* at 580-81.

[509] Moll Tr. 80-82; Mintz Tr. 550, 582, 620-22.

[510] Merger Agreement § 2.07(a)(iii).

[511] JX 2512 at 4-5.

J&J suggests that this position change meant it was off the hook for the General Surgery Milestone. Not so. The obvious goal of the General Surgery Milestone was for iPlatform to obtain FDA approval. In contrast to other provisions of the Merger Agreement, there is no evidence that 510(k) (versus another pathway) was specifically negotiated.[512] That is because at the time of the Merger Agreement, a "510(k) process" was the "only logical pathway for a robotic device."[513] When that understanding changed four month after the merger, J&J viewed the availability of De Novo (rather than PMA) as a victory.[514]

Yet, the iPlatform General Surgery Milestone expressly contemplates "510(k) premarket notification[]," which was no longer an option for iPlatform post-pathway shift.[515] To address this wrinkle in its breach of contract claim, Fortis presents an implied covenant theory.[516] It asserts that after the FDA's pathway change, the

[512] DeFonzo Tr. 363-64 (testifying that the parties "never even discussed" a non-510(k) pathway); Moll Tr. 58-59. J&J originally argued that this term was "highly negotiated." Defs.' Pre-trial Br. (Dkt. 504) 2. It did not press that argument after trial.

[513] Moll Tr. 58-59.

[514] Shen Tr. 1174; Wittwer Tr. 1953.

[515] Merger Agreement § 2.07(a)(iii). As noted above, the subsequent umbrella milestones could be obtained through 510(k) if iPlatform received De Novo clearance. *See supra* note 282 and accompanying text; Wittwer Tr. 1949.

[516] PTO ¶ 5. Fortis also advanced a mutual mistake claim that was also premised on the change in FDA policy regarding the availability of the 510(k) pathway for iPlatform. *Id.* Because documents Fortis sought through a FOIA request were not produced in time for trial, Fortis withdrew its mutual mistake claim. *See* Dkts. 525, 527.

implied covenant of good faith and fair dealing required J&J to pursue De Novo approval instead.[517] I agree.[518]

Implied Covenant. "The implied covenant [of good faith and fair dealing] is inherent in all contracts."[519] It "embodies the law's expectation that 'each party to a contract will act with good faith toward the other with respect to the subject matter of the contract.'"[520] The implied covenant "ensures that parties do not 'frustrat[e] the fruits of the bargain' by acting 'arbitrarily or unreasonably.'"[521] "The reasonable expectations of the contracting parties are assessed at the time of contracting."[522]

At the time the Merger Agreement was signed, all parties assumed that 510(k) would be an available pathway for iPlatform.[523] The FDA had indicated in October 2018 that iPlatform could receive 510(k) clearance with the appropriate clinical data

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[517] Pl.'s Opening Post-trial Br. 130-31.

[518] In my decision denying J&J's motion to dismiss the implied covenant claim, I noted that this is precisely the sort of situation where the "implied covenant comes into play." Mem. Op. Regarding the Defs.' Mot. to Dismiss (Dkt. 44) ("MTD Mem. Op.") 38. That observation remains true after trial.

[519] *Baldwin v. New Wood Res. LLC*, 283 A.3d 1099, 1116 (Del. 2022) (citation omitted).

[520] *Sheehan v. Assured P'rs, Inc.*, 2020 WL 2838575, at *11 (Del. Ch. May 2020) (quoting *Allied Cap.*, 910 A.2d at 1032).

[521] *Baldwin*, 283 A.2d at 1116 (quoting *Dieckman v. Regency GP LP*, 155 A.3d 358, 367 (Del. 2017)).

[522] *Dieckman*, 155 A.3d at 367.

[523] *See* JX 3253 at 1 (contemporaneous notes of meeting about regulatory affairs from a May 14, 2020 call where Kozak says: "During acquisition [we] had assumed 510k was appropriate.").

and predicate device.[524] It warned only that 510(k) might be unavailable because the proposed predicate device (a da Vinci robot) lacked a bronchoscope and Auris had listed a bronchoscopy indication for iPlatform.[525] Auris resolved this mismatch in its subsequent submission by withdrawing bronchoscopy from iPlatform's planned indication and selecting a more apt da Vinci predicate.[526] Neither Auris nor J&J had reason to believe that a more onerous pathway would be required.[527] In

[524] JX 743 at 3 ("While our review of your pre-submission does not imply that your future submission will necessarily be approved or cleared, FDA intends that this feedback will not change, provided that the information submitted in a future IDE or marketing application is consistent with that provided in this pre-submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness."); *id.* at 5-6.

[525] *Id.* at 4 ("You propose the da Vinci Xi K131861 as the predicate device. While the Indications for Use IFU statements of your subject device and your predicate appear to be similar the intended use of your subject device does not appear to be the same as your proposed predicate device[.] For example your proposed predicate is not intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures and does not contain a bronchoscope."); *id.* at 1; *see supra* notes 70-71 and accompanying text.

[526] JX 2468 at 5 ("[G]iven FDA's concern of using a predicate not indicated for bronchoscopic procedures, Auris has decided to remove the use of a bronchoscope from the initial submission."); Mintz Tr. 604-06 ("Question: 'Was [] the FDA telling Auris it would not approve iPlatform under the 510(k) pathway?' Mintz: 'It was not . . . They're pointing out that the da Vinci Xi does not have bronchoscopic capability . . . so we removed that from our indications for use. . . . . There's another da Vinci 510(k) that uses a robotic bed in conjunction with the system, and that was a more appropriate predicate. So we adjusted our submission to use that more appropriate predicate.'").

[527] *See In re El Paso Pipeline P'rs, L.P. Deriv. Litig*., 2014 WL 2768782, at *18 (Del. Ch. June 12, 2014) (observing that the implied covenant of good faith and fair dealing is properly invoked where "the parties simply failed to foresee the need for the term and, therefore, never considered to include it"); *see also Nemec v. Shrader*, 991 A.2d 1120, 1128 (Del. 2010).

fact, J&J was surprised in August 2019 when it learned that Verb had to follow the De Novo pathway instead of 510(k).[528]

J&J argues that requiring 510(k) approval was a material term to the Merger Agreement because the specific pathway affects the time to market, the resources required, and the deal value.[529] But there is no evidence that the parties bargained for 510(k) instead of De Novo.[530] J&J knew pre-merger that the FDA required extensive clinical testing for iPlatform to secure 510(k) approval.[531] Though De Novo approval is generally more onerous, the primary difference for iPlatform was FDA review time, which J&J predicted would only add two months of delay.[532] The FDA required iPlatform to submit clinical testing data under either the 510(k) or De Novo pathway.[533]

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[528] *See* JX 2512 at 4-5.

[529] Defs.' Answering Post-trial Br. 51-53.

[530] *See supra* note 512; *cf. Aspen Advisors LLC v. United Artists Theatre Co.*, 843 A.2d 697, 707 (Del. Ch. 2004) (explaining that the implied covenant will not fill a gap if the parties discussed and rejected it), *aff'd*, 861 A.2d 1251 (Del. 2004).

[531] *See* JX 1284 at 4, 12; JX 1504 at 5.

[532] JX 2396 at 15 (predicting a De Novo review would change Verb's launch from April 2022 to June 2022); *see also* Wittwer Tr. 1949-50 ("Per FDA regulation, a 510(k) is a 90-day review clock. And a De Novo application is a 150-day review time."); Wittwer Rep. ¶¶ 158-60 (opining that the shift to De Novo review caused an approximately 60 day delay). Wittwer's opinion was reliable. In addition to her educational and professional background, she has submitted and received FDA clearance on over fifty 510(k) applications and three De Novo applications. Wittwer Rep. ¶ 10.

[533] *See* JX 2396 at 12 (J&J concluding there was "[n]o significant timeline differences" for Verb to achieve De Novo "as compared to a 510(k)"); Tillman Tr. 2823-24 (acknowledging

Had the parties known that 510(k) would become unavailable for RASDs, they logically would not have listed 510(k) as the method of obtaining regulatory approval in the Merger Agreement.[534] The Merger Agreement lacked a term to address what would occur if the 510(k) pathway were closed to iPlatform. When this change arose, however, J&J had an implied obligation—at least for the iPlatform General Surgery Milestone—to use commercially reasonable efforts to achieve De Novo clearance. Doing so would facilitate 510(k) approval for the subsequent milestones, which I address next.[535] But J&J failed to utilize such diligence.[536] It cannot avoid liability by scapegoating an unforeseen policy change that had an immaterial effect on the time and cost for iPlatform to gain FDA clearance.[537]

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that iPlatform's 510(k) process would be in the "minority of 510(k) submissions that require clinical data").

[534] *See Oxbow Carbon & Mins. Hldgs., Inc. v. Crestview-Oxbow Acq., LLC*, 202 A.3d 482, 506-07 (Del. 2019) (explaining that the implied covenant exists to address "unanticipated developments"); *Blaustein v. Lord Balt. Cap. Corp.*, 84 A.3d 954, 959 (Del. 2014) ("[T]he implied covenant is used in limited circumstances to include what the parties would have agreed to themselves had they considered the issue in their original bargaining positions at the time of contracting." (citation omitted)).

[535] JX 2396 at 12 ("Once De Novo classification is granted, the device can be used as predicate for future 510(k) submissions."); Wittwer Tr. 1946, 1959.

[536] *See supra* Section II.A.2.a.

[537] Because I find that Fortis has prevailed on its implied covenant claim, I need not address its alternate theory that J&J should be ordered to "negotiate in good faith" to modify the Merger Agreement from 510(k) to De Novo to "effect the original intent of the parties." Merger Agreement § 10.11; *see also id.* § 8.04(b); Pl.'s Opening Post-trial Br. 132-33.

ii. *Umbrella Milestones*

Auris also proved that J&J's breaches of the Merger Agreement were reasonably certain to have led Auris to miss four 2023 iPlatform regulatory milestones: the Upper Abdominal Milestone, the Lower Abdominal Milestone, the Urologic Milestone, and the Gynecologic Milestone. Had J&J used commercially reasonable efforts in furtherance of the iPlatform General Surgery Milestone, the 510(k) pathway would have been open. The delays caused by Project Manhattan and dysfunction from the Verb combination/integration, among other breaches, led to compounding delays that put the milestones in peril. The evidence demonstrates that each of these umbrella milestones were likely to be met had J&J provided commercially reasonable efforts and resources to iPlatform as a priority device.[538]

Upper Abdominal Milestone. The Upper Abdominal Milestone required iPlatform to receive 510(k) approval for an "upper abdominal Umbrella Procedure[]" by the end of 2023.[539] The RYGB procedure would have satisfied this milestone.[540] iPlatform was on track to achieve it.

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[538] *See* JX 2683 at 3, 26-27 (Accelerando and Cambridge November 2019 projection that iPlatform could achieve the 2023 milestones).

[539] Merger Agreement § 2.07(a)(iv); *see id.* § 10.03(uuu) (defining "Umbrella Procedure" as "any procedure or procedure category within a specialty, which represents higher complexity or risk and when cleared by the FDA includes covered procedures of less complexity or lower risk within that specialty").

[540] *See* JX 1729.

Surgeons using iPlatform successfully completed RYGBs in 12 labs between June 2019 and the first quarter of 2020—both during and after Project Manhattan.[541] Surgeons performed 21 four-arm RYGB cadaver labs from August to November 2020 with iPlatform. Four different surgeons gave iPlatform all A and B grades during the final six "repeatability" labs performed in November, which were designed to test surgical techniques refined during earlier "procedure development" labs.[542] iPlatform continued to demonstrate capability in RYGB with at least 11 cadaver labs completed in 2021. Although two surgeons gave iPlatform lower (but still adequate) ratings in these labs, three others rated iPlatform A+, A, and B in all categories.[543]

To the extent J&J argues that technical issues caused iPlatform to miss the milestone, the trial record suggests otherwise. For example, after successful cadaver labs in November 2020, Joachim (who led the iPlatform team at the time) determined there was "[a]dequate approach workspace for 4-arm [RYGB] to move forward" to clinical trials.[544] Put differently, workspace issues did not prevent iPlatform from

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[541] *See e.g.*, JX 2131 at 26-27 (June 2019 five-arm RYGB rated by physician as "nearly ready for clinical use"); JX 3047 at 57 (Nov. 2019 five-arm RYGB rated by same physician as on par with da Vinci); *see also* Pl.'s Dem. 13.

[542] JX 3603 at 7.

[543] *See e.g.*, JX 3948 at 1 (May 2021 five-arm RYGB by surgeon performing his first lab on iPlatform, rating iPlatform's performance either A or A+ across the board); *see also* Pl.'s Dem. 13.

[544] JX 3685 at 7.

proceeding to clinical trials for the four-arm procedure. This assessment was three years before the milestone deadline.[545]

Lower Abdominal Milestone. The Lower Abdominal Milestone required iPlatform to obtain 510(k) approval for a "colorectal/lower abdominal Umbrella Procedure[]" by the end of 2023.[546]

The LAR procedure could satisfy the milestone. During Project Manhattan, a KOL successfully completed it using iPlatform.[547] Between July 2019 and January 2020, surgeons performed 14 additional LAR cadaver labs using the iPlatform.[548] J&J only produced written reports for five of these labs, but all show successful results.[549] From April to June 2021, surgeons performed 15 more LAR cadaver labs

[545] J&J's insistence on a full-featured iPlatform beta that could perform RYGB for the *first* regulatory approval effectively forced iPlatform to meet the Upper Abdominal Milestone two years early. *See supra* Section II.A.2.a.iii.

[546] Merger Agreement § 2.07(a)(v).

[547] JX 2125 at 21-22; *see also* JX 1541 (March 2019 report of iPlatform "[s]uccessful access of relevant workspaces for LAR").

[548] *See* Pl.'s Dem. 13.

[549] *See id.* Records for hundreds of iPlatform labs were not produced by J&J. Fortis asks me to conclude that this amounts to spoliation, and that I should infer that the withheld or destroyed lab materials confirm iPlatform's capabilities. *See* Pl.'s Opening Post-trial Br. 119-120; *see also* Pl.'s Mot. in Limine for an Adverse Inference Due to Spoliation and/or Withholding of Evidence of iPlatform Lab Procedures (Dkt. 465). Though there are gaps in the record where information has been lost, J&J also produced a substantial amount of materials from a design history file and other records. I lack grounds to find that J&J's non-production rises to the level of reckless or intentional spoliation of evidence and decline to draw an adverse inference. *See Sears, Roebuck & Co. v. Midcap*, 893 A.2d 542, 552 (Del. 2006). At the same time, it would be inequitable to infer that iPlatform did *not* successfully perform these labs based upon J&J's failure to produce the underlying data. I

on iPlatform. Based on the 11 procedures for which J&J produced lab data, iPlatform performed well. For all but one of these 11 labs, iPlatform was rated above, equivalent to, or near da Vinci on all metrics.[550] In February 2022, a five-arm LAR was performed that overall met or exceeded da Vinci's performance.[551]

Urologic Milestone. The Urologic Milestone required iPlatform to obtain 510(k) approval for a "urological Umbrella Procedure[]" by the end of 2023.[552] Lab records show that iPlatform could perform prostatectomy and partial nephrectomy—two procedures that Auris could have used to satisfy the milestone.[553]

iPlatform demonstrated its capability to perform a prostatectomy as early as 2018.[554] Post-merger, surgeons completed 19 prostatectomy cadaver labs on iPlatform, rating iPlatform's performance as above or equivalent to da Vinci on most

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view the missing information as neutral. Even without it, Fortis proved by a preponderance of the evidence that iPlatform was on track to meet the milestones before J&J's breaches.

[550] *See e.g.*, JX 3992 at 2 (rating iPlatform A+ or A across all metrics, with "[n]o workspace/collision issues" and instrument trajectories superior to da Vinci); *see also* Pl.'s Dem. 13; Pl.'s Dem. 20 (five-arm LAR lab on iPlatform in June 2021; surgeon reporting "high[] satis[faction").

[551] Gardiner Tr. 825-27. J&J produced no records for labs after June 2021. *See* Pl.'s Dem. 13 at rows 204-35. Gardiner, however, credibly testified to his personal experience with the iPlatform system performing this procedure.

[552] Merger Agreement § 2.07(a)(vi).

[553] *See, e.g.*, JX 2610 at 3, 10 (partial nephrectomy performed with "high confidence"); JX 4013 at 3, 10 (reporting 17 prostatectomy labs "with almost all A ratings, and a good range of patients"); *see supra* notes 73, 255 (explaining these procedures).

[554] Moll Tr. 87-88; Mintz. Tr. 552-53; Gardiner Tr. 746-49 ("It worked perfectly.").

metrics.[555] In 2021, J&J concluded that iPlatform would be capable in prostatectomy.[556]

iPlatform was also successfully performing partial nephrectomies. During Project Manhattan, a KOP completed a partial nephrectomy on iPlatform and rated it "nearly ready for clinical use."[557] Two more partial nephrectomy cadaver labs were completed in 2019 with strong results.[558] From July to December 2021, surgeons completed 12 more partial nephrectomy cadaver labs on iPlatform. Based on the subset of lab results J&J produced, these procedures were also successful and the iPlatform system was rated equivalent to da Vinci on most metrics.[559]

Gynecologic Milestone. The Gynecologic Milestone required iPlatform to obtain 510(k) clearance for a "gynecological Umbrella Procedure[]" by the end of 2023.[560] Auris intended to satisfy the milestone with a hysterectomy indication.

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[555] *See* JX 4013 at 10 (17 surgeons giving almost all A ratings and a few Bs); Gardiner Tr. 812-13; *see also* Pl.'s Dem. 13; Pl.'s Dem. 20 at 4 (two surgeons rating iPlatform with A+s, As, and a few Bs across relevant metrics during five prostatectomies each on iPlatform, with three other surgeons giving similar ratings during one prostatectomy each).

[556] JX 4129 at 18 ("Beta system will be capable in Prostatectomy[.]").

[557] JX 2131 at 21-22.

[558] *See* JX 2610 at 10 (surgeon writing: "Everything feels like you could go to market today, the motion of tools feels good and the workspace is great."); Gardiner Tr. 797-98 (recalling watching this procedure); *see also* Pl.'s Dem. 13.

[559] Pl.'s Dem. 13; *see also* Gardiner Tr. 821-22 (describing his performance of these procedures).

[560] Merger Agreement § 2.07(a)(vii).

During Project Manhattan, a KOP successfully completed a hysterectomy with iPlatform's alpha version.[561] This procedure was especially notable because it was the first using iPlatform's sixth arm.[562]

In total, iPlatform completed at least five successful hysterectomy cadaver labs.[563] If replicated, these procedures would show that iPlatform was safe and effective in hysterectomy from a regulatory standpoint.[564] J&J concluded in September 2021 that iPlatform was expected to be capable in hysterectomy.[565]

iii. *GI Milestone*

The GI Milestone required either iPlatform or Monarch to secure 510(k) clearance for "Endoscopic Submucosal Dissection (ESD)" by the end of 2023.[566] At the time of the merger, it was expected that the milestone could be met by the deadline with iPlatform.[567]

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[561] JX 2131 at 27-28.

[562] *Id.* at 8-9, 27-28; *see also* Mintz Tr. 596-98; Pl.'s Dem. 8 (video of the procedure).

[563] JX 2131 at 27-28; JX 2610 at 11 (surgeon: "This is so much easier than what I currently do."); Pl.'s Dem. 13.

[564] Wittwer Tr. 1958.

[565] JX 4129 at 19 ("Beta system expected to be capable in Hyster[e]ctomy[.]").

[566] Merger Agreement § 2.07(a)(viii). ESD is a procedure using an endoscope to remove precancerous and cancerous areas in the GI tract. *See Endoscopic Submucosal Dissection*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/endoscopic-submucosal-dissection (last visited August 31, 2024).

[567] JX 1729 at 16 (projecting Q2 2023 for iPlatform GI indication clearance and adding in a buffer time period); JX 3139 at 1 (J&J predicting a 75% chance of achieving the eighth regulatory milestone (GI) with iPlatform).

In the year after the merger, a small research team reporting to Leparmentier demonstrated the feasibility of performing ESD on either system.[568] In December—four years before the milestone deadline—the Monarch team completed a "very successful" ESD on a live pig with Auris-designed instruments that could be used on iPlatform.[569] Lepartmentier was confident at that point that the GI milestone would be met, provided that the GI team was given resources to move toward product development.[570] But J&J deprioritized GI.[571]

In a presentation to J&J leadership on April 6, 2020, the GI team recommended that ESD clearance be pursued on iPlatform first and Monarch later.[572] Lepartmentier supported this strategy, understanding that J&J intended to launch iPlatform in the near term.[573] The plan never came to fruition because of Project Manhattan and the Verb integration.

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[568] Leparmentier Tr. 1003-04.

[569] JX 2867 at 12 (report of "completed" colon ESD procedure "in a live porcine model" on Dec. 18, 2019); Leparmentier Tr. 1004-06.

[570] Leparmentier Tr. 1006.

[571] *See* JX 3091 at 3; Leparmentier Tr. 1008; *see also* JX 3451 (Shen directing the GI team to limit its efforts to "skunk R&D work"—exploratory research with minimal resources).

[572] JX 3148 at 38-40; Leparmentier Tr. 1010, 1085-86 (describing how pursuing the GI indication on iPlatform made commercial sense for customers and insurers); Lopes Tr. 2441-42 (discussing that GI capability was a "better fit" for iPlatform).

[573] Leparmentier Tr. 1010.

The ESD indication is perhaps the one for which iPlatform was least prepared to seek clearance. But J&J's failure to use commercially reasonable efforts derailed iPlatform's plan to build towards endoluminal capability. As iPlatform's MVP approach was lost, so too was its readiness to perform GI procedures.

Having failed iPlatform, one would expect that J&J would redirect its GI Milestone-related efforts to Monarch. Monarch had made strides in ESD during 2019 and 2020.[574] There is no evidence, though, that J&J tried to use Monarch for the achievement of the GI Milestone.

At trial, J&J spent little time defending its approach to the GI Milestone except to highlight iPlatform's purported technical defects. This is not compelling.[575] The record supports a finding that J&J's breach of the Merger Agreement is reasonably certain to have harmed to Fortis. Failed efforts and resulting delays snowballed, leaving iPlatform unable to timely meet the GI Milestone.

b. Net Sales Milestone

The Merger Agreement includes two net sales milestones. The first would have been met if J&J's "Robotics Net Sales" reached "$575 million in the aggregate"

[574] *See* JX 2867 at 12: Leparmentier Tr. 1004-06; JX 3075 at 17 (physician in February 2020 praising Monarch GI as an "[i]mmense improvement over traditional ESD" after completing a lab on a porcine colon).

[575] *See supra* notes 475-78 and accompanying text.

during 2022 or sooner.[576] The second could be met if "Robotics Net Sales" reached "$1,650 million in the aggregate" during 2024 or sooner.[577]

By its terms, the efforts provision in Section 2.07(e) does not apply to the net sales milestones.[578] The sole constraint for J&J with respect to the net sales milestones is in Section 2.07(e)(iii), which bars J&J from taking, or refraining from taking, actions "with the intention of avoiding . . . any Earnout Payment" or "based on taking into account the cost of making any Earnout Payment(s)."[579] Fortis proved that J&J breached this provision when J&J considered the loss of the contingent payments as a factor when directing that iPlatform combine with Verb.[580]

Fortis did not, however, prove that this breach was a reasonably certain cause of the missed net sales milestones. J&J's prioritization of Verb over iPlatform would have supported the net sales milestones since Verb sales are included. As Fortis concedes, "it often takes years for an innovative device to become profitable."[581]

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[576] Merger Agreement § 2.07(a)(ix); *see id.* § 10.03(ddd) (defining "Robotics Net Sales").

[577] *Id.* § 2.07(a)(x).

[578] *Id.* § 2.07(e)(i) (requiring J&J to use "commercially reasonable efforts to achieve each of the Regulatory Milestones").

[579] *Id.* § 2.07(e)(iii)(A)-(B).

[580] *See supra* notes 389-91 and accompanying text.

[581] Pl.'s Opening Post-trial Br. 110 (citing Grennan Tr. 2552-53; Shen Tr. 1169; JX 4495 ¶¶ 61, 65).

The fact that iPlatform was on the cusp of regulatory approval is not equivalent to it becoming commercially viable, much less profitable for J&J.[582]

4. Whether J&J Repudiated the Merger Agreement

Fortis also avers that J&J is liable for repudiating the Merger Agreement.[583] "Under Delaware law, repudiation is an outright refusal by a party to perform a contract or its conditions entitling 'the other contracting party to treat the contract as rescinded.'"[584] "Repudiation must be 'positive and unconditional.'"[585]

The purported "repudiation" Fortis complains of does not meet this standard. According to Fortis, J&J's cancelation of the iPlatform and GI regulatory milestones and the net sales milestones in April 2020 amounts to repudiation. But the write-down was not an "outright refusal" to perform.[586]

The write-down was an accounting exercise by which J&J released reserves; it was not a cancelation of the milestones. If iPlatform (or Monarch) reached any milestone in the Merger Agreement, J&J retained a contractual obligation to make a corresponding earnout payment. In addition, J&J continued to perform in the sense

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[582] *See supra* note 491 and accompanying text.

[583] *See* Pl.'s Opening Post-trial Br. 102-04.

[584] *CitiSteel USA, Inc. v. Connell Ltd. P'ship*, 758 A.2d 928, 931 (Del. 2000) (quoting *Sheehan v. Hepburn*, 138 A.2d 810, 812 (Del. Ch. 1958)).

[585] *W. Willow-Bay Court, LLC v. Robino-Bay Court Plaza, LLC*, 2009 WL 458779, at *5 (Del. Ch. Feb. 23, 2009) (quoting *Carteret Bancorp., Inc. v. Home Grp, Inc.*, 1998 WL 3010, at *6 (Del. Ch. Jan. 13, 1988)).

[586] *CitiSteel USA*, 758 A.2d at 931.

that it provided some resources to the Auris robots post-write-down. J&J may have fallen short of its efforts promise, but that is different from an outright refusal to perform.[587]

B. Fraud

Fortis contends that J&J fraudulently induced Auris to merge.[588] The elements of common law fraud are:

> (1) a false representation, usually one of fact, made by the defendant; (2) the defendant's knowledge or belief that the representation was false, or was made with reckless indifference to the truth; (3) an intent to induce the plaintiff to act or to refrain from acting; (4) the plaintiff's action or inaction taken in justifiable reliance upon the representation; and (5) damage to the plaintiff as a result of such reliance.[589]

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[587] Fortis also claims that J&J failed to provide Fortis with quarterly disclosures, in breach of Section 2.07(d)(i) of the Merger Agreement. Section 2.07(d)(i) provides that J&J must, each quarter, provide "to the Stockholder Representative . . . a reasonable written update on the status of achieving each of the Milestones, including with respect to the Regulatory Milestones, a reasonable update on the actions undertaken by [J&J] . . . pursuant to Section 2.07(e)." Fortis relegated its argument on this claim to a footnote in its opening post-trial brief. Pl.'s Opening Post-trial Br. 133 n.43. To the extent it continues to press the claim, Fortis did not prove a breach of Section 2.07(d)(i). The record reflects that Fortis was given reasonable quarterly disclosures. *See* JX 2528; JX 2530; JX 2665; JX 2978; JX 3218. Even if J&J had breached the provision, Fortis did not prove resulting damage. Moll and DeFonzo also provided information to Fortis's Advisory Board directly. *See* Salehizadeh Dep. 78-79, 86-90; *see also* Royan Tr. 428-29.

[588] PTO ¶ 3.

[589] *Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983); *see Maverick Therapeutics, Inc. v. Harpoon Therapeutics, Inc.*, 2020 WL 1655948, at *26 (Del. Ch. 2020) ("The elements of fraud and fraudulent inducement are the same.").

The fraud must be "material" and "concern an essential part of the transaction."[590] Fraud may arise through misrepresentations, concealment of material facts, or silence under a duty to speak.[591]

Fortis advances three fraud theories. First, it claims that J&J's statements about developing iPlatform and Verb in parallel were false.[592] Second, it claims that J&J misled Auris by promising a "light touch" integration into J&J.[593] And third, it claims that the Soft Tissue Ablation Milestone was not "highly certain" to be met, as J&J assured Auris.[594]

Before addressing the merits, I first resolve J&J's argument that the Merger Agreement's integration clause is a barrier to the first and second fraud theories.

1. The Integration Clause

J&J argues that Fortis's fraud claims based on parallel development and "light touch" integration are barred by the Merger Agreement's integration clause.[595] The Merger Agreement's integration clause is standard.[596] The Merger Agreement

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[590] *Maverick*, 2020 WL 1655948, at *31 (quoting *Great Hill Equity Partners IV, LP v. SIG Growth Equity Fund I, LLLP*, 2018 WL 6311829, at *33 (Del. Ch. Dec. 3, 2018)).

[591] *Stephenson*, 462 A.2d at 1074.

[592] Pl.'s Opening Post-trial Br. 88-89.

[593] *Id.* at 89-90 (quoting JX 2755).

[594] *Id.* at 90-91.

[595] Defs.' Answering Post-trial Br. 130-32.

[596] Merger Agreement § 10.07 ("This Agreement, the Escrow Agreement and the Confidentiality Agreement [] constitute the entire agreement, and supersede all prior

contains only an asymmetric anti-reliance provision in which J&J disclaimed reliance on extra-contractual representations.[597] Auris did not make a similar disclaimer.

In resolving J&J's motion to dismiss, I explained that "a standard integration clause, without anti-reliance language, cannot disclaim reliance of representations outside of the written contract."[598] I also observed that the one-way anti-reliance clause in the Merger Agreement means "Auris was permitted to rely on the defendants' assurances."[599] J&J avers that I left open the effect of the integration clause on "alleged extra-contractual promises of future intent."[600] I see no basis to deviate from my prior ruling.[601] To the extent that J&J is not bound by it or has presented different considerations, J&J's argument fails on the merits.

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agreements and understandings, both written and oral, among the parties with respect to the subject matter hereof or thereof . . . .").

[597] *Id.* § 4.08 ("Except for the representations and warranties contained in Article III [of the Merger Agreement], [J&J] and Merger Sub acknowledge that none of [Auris] or any person on behalf of [Auris] makes, and neither [J&J] nor Merger Sub have relied upon, any other express or implied representation or warranty with respect to [Auris] or any of its Subsidiaries or with respect to any other information provided or made available to [J&J] or Merger Sub in connection with the transactions contemplated by this Agreement . . . . Each of [J&J] and Merger Sub disclaims any representations and warranties other than those that are expressly set forth in Article III.").

[598] MTD Mem. Op. 22.

[599] *Id.* at 29.

[600] Defs.' Answering Post-trial Br. 130; *see also* Defs.' Pre-trial Br. 78.

[601] *See Advanced Litig., LLC v. Herzka*, 2006 WL 2338044, at *5 (Del. Ch. Aug. 10, 2006).

J&J asserts that "an integration clause alone is sufficient to bar a fraud claim based on expressions of future intent or future promises."[602] It cites two decisions in support: *Shareholder Representative Services LLC v. Albertsons Companies, Inc.* and *Black Horse Capital, LP v. Xstelos Holdings, Inc.*[603] Nevertheless, the general rule in Delaware is that "integration clauses do not operate to bar fraud claims based on factual statements not made in the written agreement."[604] "If parties fail to include unambiguous anti-reliance language, they will not be able to escape responsibility for their own fraudulent representations made outside of the agreement's four corners."[605] There is neither a recognized exception to these principles nor a reason to deviate from them here.[606]

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[602] Defs.' Answering Post-trial Br. 130 (quoting *Albertsons*, 2021 WL 2311455, at *12).

[603] *Albertsons*, 2021 WL 2311455, at *2; *see also Black Horse Cap. L.P. v. Xstelos Hldgs., Inc.*, 2014 WL 5025926, at *24-25 (Del. Ch. Sept. 30, 2014) (holding that an integration clause barred a fraud claim because the statements allegedly relied upon "were not misrepresentations of material fact . . . but rather prior parole evidence that would vary the extant terms in the subsequent integrated writings").

[604] *Kronenberg v. Katz*, 872 A.2d 568, 592 (Del. Ch. 2004); *see also* 11 Williston on Contracts § 33:24 (4th ed.), Westlaw (May 2024 update).

[605] *Abry P'rs V, L.P. v. F & W Acq. LLC*, 891 A.2d 1032, 1059 (Del. Ch. 2006).

[606] *See Trifecta Multimedia Hldgs., Inc. v. WCG Clinical Servs. LLC*, 318 A.3d 450, 466-67 (Del. Ch. 2024) (rejecting a similar argument).

On top of that, *Albertsons* and *Xstelos* are inapposite. Neither case involved a contract with a one-sided anti-reliance clause. And unlike here, the purported oral misrepresentations in those cases conflicted with the terms of the contracts.[607]

2. Parallel Pathing and Prioritization

Fortis avers that J&J's senior leadership made various false statements promising to prioritize iPlatform and develop it in parallel with Verb.[608] Most are the sort of "classically vague statements that a commercial party routinely makes during deal-making courtship."[609] They include:

- that iPlatform and Verb were "complementary";[610]
- that Auris had J&J's "resources at [its] sails" to develop iPlatform;[611]
- that J&J would spend "multiples" of what Auris alone could devote to its technology;[612]
- that iPlatform was a "priority";[613] and

[607] *Albertsons*, 2021 WL 2311455, at *2; *Xstelos*, 2014 WL 5025926, at *22.

[608] Pl.'s Opening Post-trial Br. 88.

[609] *Airborne Health, Inc. v. Squid Soap, LP*, 2010 WL 2836391, at *8 (Del. Ch. July 20, 2010).

[610] Pl.'s Opening Post-trial Br. 25 (quoting JX 838).

[611] *Id.* at 24 (quoting DeFonzo Tr. 330-31).

[612] *Id.* (quoting JX 1004).

[613] *Id.* (quoting McEvoy Tr. 2598). This is, of course, different from whether J&J treated iPlatform as a priority device in fulfilling its efforts obligation.

- that Auris could access J&J's "global candy store" of resources.[614]

Statements like these, praising one's "skills, experience, and resources," are "mere puffery and cannot form the basis for a fraud claim."[615]

Further, it is not apparent that these statements are false or were made with scienter.[616] The evidence suggests that J&J intended to provide the Auris robots with more resources than Auris had as a standalone company.[617] Auris's products were given, among other things, substantial funding, access to J&J's "global candy store,"

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[614] *Id.* (quoting JX 920).

[615] *Solow v. Aspect Res., LLC*, 2004 WL 2694916, at *3 (Del. Ch. Oct. 19, 2004) (citing *Kronenberg*, 872 A.2d at 580-81); *see also Trenwick Am. Litig. Trust v. Ernst & Young, L.L.P.*, 906 A.2d 168, 209 (Del. Ch. 2006) (explaining that "statements of expectation or opinion about the future of the company and the hoped for results of business strategies" are "generally not actionable" for fraud claims under Delaware law); *Winner Acceptance Corp. v. Return on Cap. Corp.*, 2008 WL 5352063, at *8 (Del. Ch. Dec. 23, 2008) (describing statements that one's expertise would help expand the business as "mere pun and puffery"); *Trifecta*, 318 A.3d at 463-64 (holding that statements about a party being "the best partner to accelerate growth" or that the counter-party would benefit from "collaboration, coordination and shared relationship" across thousands of clients were "non-actionable puffery"); *Earth Pride Organics, LLC v. Corona-Orange Foods Intermediate Hldgs., LLC*, 2024 WL 1905384, at *9 (Del. Ch. Apr. 17, 2024) (concluding that statements about resources to "support growth," company capabilities, and expertise "to execute against new opportunities" were the sort of pre-transaction puffery that could not support a fraud claim).

[616] *See Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 143 (Del. Ch. 2004); *see also Arwood v. AW Site Servs., LLC*, 2022 WL 705841, at *20 (Del. Ch. Mar. 9, 2022) (explaining that a plaintiff must show that false statements were made "knowingly, intentionally, or with reckless indifference to the truth" and that the speaker "intended to induce [the plaintiff's] reliance" on the alleged misrepresentation (citation omitted)).

[617] *E.g.*, JX 1150; JX 2873; McEvoy Tr. 2664-65; McEvoy Dep. 281-82; *see also* Shen Tr. 1462-63.

a dedicated "Tiger Team," and many of Verb's assets. These resources mostly came too late to support iPlatform's achievement of the regulatory milestones, or even impaired iPlatform's success. That does not, however, mean that J&J's statements were untrue.

J&J's statements about parallel pathing Verb and iPlatform are relatively less vague. They include:

- that iPlatform and Verb would be developed in "parallel";[618] and
- that J&J planned to launch both iPlatform and Verb, meaning that it had the funds to develop both.[619]

Fortis contends that J&J "never intended" to develop the two systems in parallel, as evidenced by Project Manhattan and the Ashley Management Decision.[620]

These are statements of future intent rather than present fact.[621] The record demonstrates that pre-merger, J&J was considering different options for the

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[618] Pl.'s Opening Post-trial Br. 24 (quoting Moll Tr. 40).

[619] *Id.* (citing Morano Tr. 1474).

[620] *Id.* at 25.

[621] *See Great Lakes Chem. Corp. v. Pharmacia Corp.*, 788 A.2d 544, 554 (Del. Ch. 2001) ("Predictions about the future cannot give rise to actionable common law fraud. Nor can expression of opinion." (citation omitted)); *MicroStrategy Inc. v. Acacia Rsch. Corp.*, 2010 WL 5550455, at *15 (Del. Ch. Dec. 30, 2010) ("Generally, prior oral promises or statements of future intent do not constitute 'false representation[s] of fact' that would satisfy the first element of fraudulent misrepresentation."); *Winner Acceptance*, 2008 WL 5352063, at *10 ("This Court looks with particular disfavor at allegations of fraud when the underlying utterances take the form of unfulfilled promises of future performance."); *Carrow v. Arnold*, 2006 WL 3289582, at *9 (Del. Ch. Oct. 31, 2006) ("Generally, prior oral promises or statements of future intent do not constitute 'false representation[s] of

respective programs. J&J viewed iPlatform as a potential a backup for Verb—Shen's so-called "bullet proof strategy."[622] Before closing, J&J evaluated developing both systems and launching them as complementary offerings focused on different indications or markets.[623] I cannot conclude that J&J's statements about parallel pathing were made without any intention of performing.[624]

Project Manhattan was contrary to J&J's promise to devote commercially reasonable efforts to iPlatform. But the contours of Project Manhattan as a direct comparison between iPlatform and Verb were set after closing. J&J had the funds to develop and launch both robots, even if the Ashley Management Decision made

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fact' that would satisfy the first element of fraudulent misrepresentation."), *aff'd*, 933 A.2d 1249 (Del. 2007).

[622] JX 1630; *see supra* note 218 and accompanying text.

[623] *E.g.*, JX 1363 at 9 (J&J in February 2019 projecting launches for iPlatform and Verb); JX 664 at 4 (Shen in September 2018 describing "a potential segmentation play" of Verb and iPlatform, stating that the programs "can be complementary," and that having both would be a "'Fail Safe' plan for [J&J's] robotic[s] strategy"); *see also* JX 1557 at 2 (J&J telling the FTC post-closing that the systems were "complementary" because "Verb will pursue laparoscopic procedures with a focus on those that benefit from advanced instrumentation, and iPlatform will pursue complex procedures that benefit from concomitant endoscopic and laparoscopic techniques").

[624] *See Grunstein v. Silva*, 2009 WL 4698541, at *13 (Del. Ch. Dec. 8, 2009) ("Courts . . . will convert an unfulfilled promise of future performance into a fraud claim if particularized facts are alleged that collectively allow the inference that, at the time the promise was made, the speaker had no intention of performing."); *see also Stevanov v. O'Connor*, 2009 WL 1059640, at *12 (Del. Ch. Apr. 21, 2009).

this a less likely outcome.[625] Parallel pathing was one of the three outcomes of Project Manhattan contemplated by Shen.[626]

J&J ultimately chose to use iPlatform to prop up Verb. Some J&J officers, like Gorsky, may have viewed "meshing" the robots as an upside of the merger. As of closing, though, it was just a scenario under consideration. The final decision to merge iPlatform with Verb was made only after Project Manhattan when the J&J Board approved it. Although J&J's conduct regarding iPlatform fell short of its contractual efforts obligations, Fortis did not prove that J&J's pre-closing statements about parallel pathing constitute fraud.

3. "Light Touch" Integration

Fortis also avers that J&J defrauded it by making representations about Auris's anticipated place within the overall J&J organization. These statements include:

- that J&J would "[p]reserve [Auris's] entrepreneurial innovation culture";[627]

[625] *See* Shen Tr. 1247-48 (explaining that despite the budget challenge by McEvoy, J&J was financially able to develop both systems in parallel if the business decision was made to do so).

[626] JX 1702 at 3 ("Develop both systems in parallel and the[n] make the final commercialization decision.").

[627] Pl.'s Opening Post-trial Br. 31 (quoting JX 838 at 6); *see also id.* (quoting Moll. Tr. 38).

- that J&J would "retain [Auris's] leadership / team by creating a semi-autonomous model";[628]
- that J&J would be "deferential" to Moll;[629] and
- that, unlike in prior mergers, it was going to "do[] Silicon Valley well . . . this time."[630]

Fortis did not prove that these statements were fraudulent. Several are the sort of fluffy platitudes made during negotiations that "no rational prospective investor . . . would find material."[631] J&J's integration of Auris might not have had the "light touch" Auris anticipated, but it seems that Auris had a different subjective view of lightness than J&J.[632]

Other statements are not false. Auris personnel were kept in some key leadership positions and maintained a measure of control over certain functions, as J&J intended.[633] In many other ways, Auris's autonomy was understandably lost.

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[628] *Id.* (quoting JX 838 at 6).

[629] *Id.* (quoting DeFonzo Tr. 328).

[630] *Id.*

[631] *Lazard Debt Recovery GP, LLC. v. Weinstock*, 864 A.2d 955, 971 (Del. Ch. 2004) (finding that statements touting an "ideal work environment" and "unique resources" were "at best enthusiastic puffery"); *Squid Soap*, 2010 WL 2836391, at *8 (explaining that statements of "corporate optimism" cannot support a fraud claim); *see supra* note 615 and accompanying text.

[632] *E.g.*, JX 1299 at 8 (J&J talking points explaining to Auris "some aspects that will need to be integrated into J&J post-close such as financial reporting, and HR").

[633] *E.g.*, McEvoy Tr. 2597; Pl.'s Dem. 7; *cf. Trifecta*, 318 A.3d at 458, 464-65 (holding that it was reasonably conceivable an explicit promise that a target could "operate independently (including all local corporate functions)" was fraud where the acquirer

Auris could not justifiably expect that it would retain the same culture and independence it enjoyed as a startup after being acquired by a multi-billion-dollar global company like J&J. Nor did J&J represent as much.

4. Certainty of the Soft Tissue Ablation Milestone

Fortis's third fraud theory is markedly different than the others. On January 24, 2019, while working to convince Auris to sell, Gorsky (with the guidance of Morano and Kozak) offered the $100 million Soft Tissue Ablation Milestone to Moll. Gorsky told Moll that there was such a "high certainty" of achieving the milestone that J&J viewed it as an "'effective' up front" payment.[634] This representation was false because the milestone was not remotely certain to be met.[635]

prevented the target's personnel from speaking with potential customers immediately after closing).

[634] JX 1228 at 5 (Gorsky talking points delivered to Moll on January 24, 2019, referencing the milestone as part of the total up front consideration); *id.* at 6 (explaining that J&J had included the milestone "to be responsive to [Auris's] request" and that J&J thought Auris would "view [it] as relatively certain and near-term"); *see also* Kozak Tr. 1572-73; Moll Tr. 51 (testifying that Gorsky described "a highly likely target for achievement by the team because it was a very simple integration" between Monarch and the FLEX device).

[635] Kozak testified that J&J viewed the milestone as "achievable." Kozak Tr. 1618; *see also* JX 1239 at 3 (discussing the achievability of the milestone by end of July 2022). That is very different from being "'effective' up-front consideration." JX 1228 at 5.

Whether Gorsky's statement is an "overt misrepresentation" is borderline.[636] But it is undoubtedly "active concealment of material facts."[637] When J&J's representation about the milestone's certainty was made, J&J knew that a patient in its NeuWave clinical study had recently died.[638] A for-cause, on-site investigation had been launched by the FDA.[639] On January 24—two weeks before Gorsky and Moll spoke—J&J's point of contact for the study "briefed" J&J's Auris deal team (including Kozak) on the "patient death that [wa]s currently under investigation."[640] The investigation risked substantial delay.[641] Yet J&J waited until after closing to tell Auris.

Gorsky's statement was intended to induce Auris to agree to a contingent payment and Auris justifiably relied on it.[642] Auris was damaged as a result of its

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[636] *In re Am. Int'l Grp., Inc., Consol. Deriv. Litig.*, 965 A.2d 763, 804 (Del. Ch. 2009), *aff'd sub nom. Teachers.' Ret. Sys. Of La. v. PricewaterhouseCoopers LLP*, 11 A.3d 228 (Del. 2011) (TABLE).

[637] *Id.*

[638] *See* JX 1901 at 30.

[639] *See* JX 1673; Bryant Tr. 2519-20; *supra* note 172 and accompanying text.

[640] JX 1182 (Kozak updating Morano in January 2019, discussing that "a sensitivity [analysis] will be run to understand impact to valuation" from the patient death under investigation); *see also* JX 1171; JX 1673.

[641] *See* Wittwer Rep. ¶¶ 95-101; Wittwer Tr. 1966-68; *see also* JX 1213.

[642] *See* Hebert Tr. 1400-01; Kerrey Tr. 1428-29; Royan Tr. 1378-79; *see also* JX 1249 at 3 (Moll on Jan. 24, 2019 calling the Monarch milestone a "chip shot"). J&J argues that "[t]here is no document that corroborates" the Auris directors' testimony that they relied on J&J's representations. Defs.' Answering Post-trial Br. 121 n.9. It is unclear why J&J feels that the directors' credible testimony is insufficient. The parties' negotiating history

reliance.[643] Destroying the value of the milestone was a direct and proximate result of J&J's fraud.[644] Auris never would have agreed to this milestone had it known about the patient death, since uncertainty persisted over the safety of FLEX and the timeline to clear regulatory hurdles.[645] It would have demanded a higher upfront payment instead.[646]

III. REMEDY

Fortis is entitled to damages for J&J's breaches of the efforts provision in the Merger Agreement as they relate to the iPlatform regulatory milestones and GI Milestone. It is also entitled to damages for J&J's fraud as it relates to the Soft

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further supports that the $100 million milestone as "up front" consideration was important in Auris's decision to merge. *See* Moll Tr. 51-52; DeFonzo Tr. 390-392.

J&J has asked for adverse inferences on the Auris board's reliance since two members (Salehizadeh and Hebert) failed to preserve text messages. Defs.' Mot. for Spoliation Sanctions (Dkt. 328). On June 5, 2023, I ordered the directors' remaining responsive texts to be produced and reserved decision on whether they recklessly spoliated evidence. After reviewing the trial record, I decline to issue sanctions. I see no basis to conclude that either individual recklessly (much less intentionally) spoliated evidence.

[643] At some point, the fact of the patient death became public. *See* JX 976. A report dated December 3, 2018 is on the FDA's website. *Id.* at 3. This does not excuse J&J's fraud. It is unknown when the report was posted. Even if it were made public pre-merger, Auris would have had no reason to search the FDA's website for information about problems with the NeuWave study.

[644] *See Maverick*, 2021 WL 1592473, at *9.

[645] *See* DeFonzo Tr. 391-92 ("[I]f we were aware of that, I don't think we would have accepted that milestone."); Moll Tr. 177 (testifying the FLEX complications put in doubt whether the "milestone was even relevant"); *see also* JX 2339; Leparmentier Tr. 996-97.

[646] *See* Moll Tr. 51-52; DeFonzo Tr. 391-92; *see also supra* note 642.

Tissue Ablation Milestone. Once liability is established, "this court has broad discretion to tailor a remedy to suit the situation as it exists."[647]

Under Delaware law, the standard remedy for breach of contract "is based upon the reasonable expectations of the parties *ex ante*."[648] Damages for fraud are similar. "[T]he recipient of a fraudulent misrepresentation is entitled to recover as damages . . . the pecuniary loss to [it] of which the misrepresentation is a legal cause."[649] "Such expectation—or benefit-of-the-bargain—damages are measured by the amount of money that would put the plaintiff in the position it would have held if the defendant's representations were true" or if the defendant had performed as promised.[650]

A. Contract Damages

J&J must indemnify Fortis for losses "arising from or relating to" any "breach of or failure to perform" under the Merger Agreement.[651] Fortis proved that J&J

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[647] *Gilliland v. Motorola, Inc.*, 873 A.2d 305, 312 (Del. Ch. 2005) (citation omitted).

[648] *Siga II*, 132 A.3d at 1111 (quoting *Duncan v. Theratx, Inc.*, 775 A.2d 1019, 1022 (Del. 2001)).

[649] *NetApp, Inc. v. Cinelli*, 2023 WL 4925910, at *17 (Del. Ch. Aug. 2, 2023) (quoting Restatement (Second) of Torts § 549(1)).

[650] *Id.* at *17 (citing *Siga II*, 132 A.3d at 1130); *see also Comrie v. Enterasys Networks, Inc.*, 837 A.2d 1, 17 (Del. Ch. 2003) ("Th[e] principle of expectation damages is measured by the amount of money that would put the promisee in the same position as if the promisor had performed the contract." (*citing Duncan*, 775 A.2d at 1022)).

[651] Merger Agreement § 8.02. Although Section 8.02(c) caps damages at $170,000,000 except for intra-contractual fraud, Section 8.05(b) carves out the "right to Earnout

breached the Merger Agreement and the implied covenant of good faith and fair dealing, leading it to miss the iPlatform and GI regulatory milestones. Fortis has put forward two measures of calculating its damages from these breaches.

First, it requests monetary damages equivalent to the full amount of each milestone. The milestones for which Fortis is entitled to damages and the associated payments are:

Milestone	Payment
General Surgery Milestone	$400,000,000
Upper Abdominal Milestone	$150,000,000
Lower Abdominal Milestone	$150,000,000
Urologic Milestone	$150,000,000
Gynecologic Milestone	$150,000,000
GI Milestone	$150,000,000

Together, these milestones total $1,150,000,000.[652]

In the alternative, Fortis proposes an approach to damages in which each milestone payment is weighted by the parties' estimated probability of achievement at the time of the merger. It offers the expert opinion of Dr. Richard Manning, an economist, in support.[653] Manning opined that the court can reasonably measure

payments and the rights and obligations of the parties pursuant to Section 2.07." *Id.* §§ 8.02(c), 8.05(b). Fortis's contract claims are under Section 2.07.

[652] Fortis seeks a total of $2,350,000,000 in breach of contract damages, which is the amount of potential earnout payments. *See* Pl.'s Opening Post-trial Br. 101.

[653] Manning is a managing director at Intensity, LLC, where he works as an economist. He earned his M.A. and Ph. D. degrees in economics from the University of Chicago. He regularly provides consulting and expert services on breach of contract, economic

what Auris expected to gain using the probability-weighted milestone values assigned by the parties.[654] Auris's estimated probabilities of success are from a February 2019 valuation prepared by its financial advisor Centerview Partners, which reflects input from Auris management.[655] J&J's estimates are from a January 2019 valuation model prepared by J&J and presented to its Board.[656] Manning also calculated a blended approach by averaging the parties' probability assignments.[657]

Manning's alternative approach is warranted here. Contract damages should "put the promisee in the same position as if the promisor had performed the contract."[658] At the time of the merger, neither party anticipated that the milestone payments were a certainty. They separately assigned each iPlatform regulatory milestone a probability of achievement. The risk-adjusted probabilities assessed by the parties and their advisors reasonably reflect the likelihood that the milestones would have been achieved if J&J complied with its efforts obligation.

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valuation, competition economics and antitrust, intellectual property, business strategy, and public policy. *See* JX 4493 ("Manning Rep.") 11.

[654] Manning Tr. 2051-52; Manning Rep. ¶ 115; *see* Pl.'s Dem. 15 at 14.

[655] Manning Rep. ¶¶ 115(a), 177; JX 1413 (Centerview Feb. 12, 2019 presentation).

[656] Manning Rep. ¶¶ 115(b), 173-74; JX 2873 (J&J Jan. 2019 "BoD model" with native Excel attachment).

[657] Manning Rep. ¶ 115(c); *see* Pl.'s Dem. 15 at 14.

[658] *Comrie*, 837 A.2d at 17 (citation omitted).

The best evidence of how the milestones would have fared absent J&J's breaches of the Merger Agreement is the parties' contemporaneous risk-adjusted probabilities of success.[659] These estimates provide a credible, responsible basis to calculate Fortis's damages.[660] Auris had deep knowledge of its own ability to reach the milestones. J&J's independent estimate came after (or during) multiple rounds of due diligence and was remarkably close to Auris's predictions.[661] These probabilities are:[662]

Milestone	Auris Probability	J&J Probability	Blended Probability
General Surgery Milestone	65%	85%	75%
Upper Abdominal Milestone	85%	75%	80%
Lower Abdominal Milestone	85%	75%	80%
Urologic Milestone	85%	75%	80%
Gynecologic Milestone	85%	75%	80%
GI Milestone	85%	75%	80%

J&J did not offer a separate approach to calculating damages, other than to argue that Fortis is entitled to none. Its rebuttal expert, Dr. James E. Malackowski,

[659] JX 3139 (J&J's Apr. 3, 2020 estimate); JX 1413 (Centerview's Feb. 12, 2019 estimates based on Auris management).

[660] *See Beard Rsch., Inc. v. Kates*, 8 A.3d 573, 613 (Del. Ch. 2010) (explaining that mathematical certainty in damages is not required "where a wrong has been proven and injury established"), *aff'd*, 11 A.3d 749 (Del. 2010); *see also SIGA Techs., Inc. v. PharmAthene, Inc*., 67 A.3d 330, 351 n.99 (Del. 2013).

[661] *See* Grennan Tr. 2560-61.

[662] JX 1413; JX 3139; *see* Manning Rep. at Attachments B-2, B-3, B-4.

criticized Manning's approach.[663] Malackowski opined that Manning's analysis used an outdated pre-diligence model created by J&J, which relied on inaccurate projections from Auris and did not account for "undisclosed risks" negatively affecting Auris's value.[664]

None of these points are persuasive. J&J's own communications state that the differences between the pre-diligence model presented to its Board (that Manning relied on) and a updated post-diligence updated model (that Malackowski addressed) are "slight."[665] The changes have no meaningful effect on Fortis's damages.[666] The probabilities of success J&J assigned to the relevant milestones remained the same.[667] J&J's projections were based on extensive due diligence and reliance on an outside advisor. These estimates supported an essential part of the deal.[668] And

[663] Malackowski is the co-founder and senior managing director of Ocean Tomo, LLC, which provides financial expert, management consulting, and advisory services. He is an experienced testifying expert on subjects including valuation, lost profits, and venture financing including expected risk / return. He has a bachelor's degree in accounting from the University of Notre Dame and is a registered Certified Public Accountant. Malackowski Rep. 5-6.

[664] *Id.* at 37-58.

[665] JX 2873 ("The overall EBIT differences are slight – only about $200MM cumulative.").

[666] *Compare* Malackowski Rep. Figure 12, *with id.* at Figure 13.

[667] *Compare id.* at Figure 13, *with* Pl.'s Dem. 15 at 14.

[668] *See* Manning Tr. 2061-62 (opining that it was reasonable to conclude that the parties' estimates of success were reliable since they were "an essential part of the transaction they were engaged in").

there is also no credible basis in the record to find that material risks affecting iPlatform were hidden from J&J by Auris.[669]

Based upon the parties' contemporaneous valuations, Fortis's potential damages can be calculated using (1) J&J's assessment; (2) Fortis's assessment; or (3) a blended probability. I believe that the third approach is appropriate. It considers the plaintiff's view of damages at the time of the breach, while accounting for J&J's more conservative view of the 2023 milestones.[670]

Fortis's damages for breach of contract, by milestone and based upon a blend of the probabilities contemporaneously assigned by the parties, are:

Milestone	Payment	Blended Probability	Damages
General Surgery Milestone	$400,000,000	75%	$300,000,000
Upper Abdominal Milestone	$150,000,000	80%	$120,000,000
Lower Abdominal Milestone	$150,000,000	80%	$120,000,000
Urologic Milestone	$150,000,000	80%	$120,000,000
Gynecologic Milestone	$150,000,000	80%	$120,000,000
GI Milestone	$150,000,000	80%	$120,000,000
TOTAL			**$900,000,000**

[669] *See supra* notes 104, 109, 118-19, 471-72 and accompanying text.

[670] *NetApp*, 2023 WL 4925910, at *17 (citing *Stephenson*, 462 A.2d at 1076).

B. Fraud Damages

Fortis proved that J&J committed fraud with respect to the Soft Tissue Ablation Milestone.[671] Fortis has the burden to present a reasonable method to calculate fraud damages.[672]

Fortis offers two measures of damages for its fraud claim: (1) rescissory damages or (2) benefit of the bargain (i.e., expectation) damages.[673] Rescissory damages are "the monetary equivalent of rescission" and intended to restore parties to the economic positions they would have held had the challenged transaction not occurred.[674] Benefit of the bargain damages "are equal to 'the difference between the actual and the represented values of the object of the transaction.'"[675] Since J&J's fraud concerns a single milestone, I believe that the benefit of the bargain approach is more suitable to compensate Fortis than the "exceptional" remedy of rescissory damages.[676]

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[671] *See* JX 1215 at 5; *supra* Section II.B.4.

[672] *See, e.g.*, *Maverick*, 2021 WL 1592473, at *9.

[673] Pl.'s Opening Post-trial Br. 97.

[674] *Lynch v. Vickers Energy Corp.*, 429 A.2d 497, 501 (Del. 1981), *overruled in part on other grounds, Weinberger v. UOP, Inc.*, 457 A.2d 701, 714 (Del. 1983).

[675] *LCT Cap., LLC v. NGL Energy P'rs LP*, 249 A.3d 77, 91 (Del. 2021) (quoting *Stephenson*, 462 A.2d at 1076).

[676] *See Universal Enters. Grp., L.P. v. Duncan Petroleum Corp.*, 2013 WL 3353743, at *15-16 (Del. Ch. July 1, 2013) (explaining that Delaware courts are reluctant to award rescissory damages, particularly for transactions occurring years prior where intervening events have occurred) (citations omitted).

The purpose of expectation damages is to put Fortis "in the position it would have held if [J&J's representations] were true."[677] Unlike rescissory damages, which are based on undoing a fraudulent transaction, expectation damages remit to Fortis the value of the object it was fraudulently promised.[678] Damages are equal to the difference between the actual and represented values of the object of the fraudulent transaction—here, the Soft Tissue Ablation Milestone.

The actual value of the milestone is the reduced probability of reaching it due to the material information J&J kept from Fortis. Manning treated the actual value as $0, on the assumption that J&J's misrepresentation made the earnout payment associated with the milestone unattainable. I adopt this value. Fortis has proven that the milestone became unattainable due to the cumulative effect of J&J's fraud.

The represented value of the milestone is based on Auris's reasonable expectation of its value at the time of the breach—i.e., the risk-adjusted probability of reaching the milestone. Manning calculated this figure using the expected net present value (eNPV) of the milestone at the time of the merger.[679] He considered

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[677] *NetApp*, 2023 WL 4925910, at *17 (citing *Siga II*, 132 A.3d at 1130); *Strassburger v. Earley*, 752 A.2d 557, 579 (Del. Ch. 2000) (explaining that expectations are measured at the time of the transaction).

[678] *See Maverick*, 2021 WL 1592473, at *9 ("Benefit of the bargain damages are equal to the difference between the actual and represented values of the object of the fraudulent transaction. This method should put the plaintiff in the same position that the plaintiff would have been in if the defendant's representations had been true." (citation omitted)).

[679] Manning Rep. ¶¶ 181-85.

three valuation scenarios representing Auris's reasonable expectation of the contingent payment. First, he assessed an eNPV for the milestone using Centerview's February 2019 valuation.[680] Second, he assessed an eNPV for the milestone using J&J's January 2019 model as presented to its Board.[681] Finally, he calculated an eNPV for the milestone using a blended average of Centerview and J&J's risk-adjusted values.[682]

Centerview derived a present value of the contingent payments based on an estimated probability of success for each milestone.[683] The estimated probability of successful results multiplied by the contingent payment amount results in an expected payment for each milestone. To calculate the present value of each milestone, Centerview discounted each expected payment back to March 31, 2019 using a 10.5% discount rate.[684] Centerview's risk-adjusted eNPV for the Soft Tissue Ablation Milestone is $58,000,000 using an 85% probability of achievement.[685]

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[680] *Id.* ¶ 183; *see id.* ¶¶ 161, 177; JX 1413.

[681] Manning Rep. ¶ 184; *see id.* ¶¶ 173-74; JX 2873.

[682] Manning Rep. ¶ 182.

[683] JX 1413; *see* Manning Rep. ¶¶ 177-79.

[684] JX 1413 ("Valuation as of 3/31/19 based on 10.5% discount rate using mid-year convention."); Manning Rep. ¶ 177.

[685] Manning Rep. Attachment D-2; *see* JX 1413.

Like Centerview, J&J assessed the present value of the contingent payments using an estimated probability of success for each milestone.[686] The expected payment amount was calculated by multiplying the estimated probability of success by the contingent payment amount. J&J discounted each expected payment back to April 1, 2019 using a 9.5% discount rate.[687] The risk-adjusted eNPV for the Soft Tissue Ablation Milestone using J&J's model is $63,731,495 based on an 85% probability of achievement.[688]

Manning's blended average of the Centerview and J&J risk-adjusted eNPVs is $60,865,748.[689] The difference between the represented value of the Monarch Soft Tissue Ablation Milestone and the actual value ($0) is $60,865,748. I adopt this figure as the most responsible estimate of Auris's reasonable expectation of the Monarch Soft Tissue Ablation Milestone's value at the time of the merger. Consistent with my approach to contract damages, the blended value strikes a responsible balance.

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[686] JX 2873 (Tab: "Contingent Consideration"); Manning Rep. ¶¶ 174-75.

[687] Manning Rep. ¶ 174; JX 2873 (Tab: "Corporate Model (Stock)").

[688] Manning Rep. ¶ 192; *id.* at Attachment D-3; JX 2873 (Tabs: "Input," "Contingent Consideration").

[689] Manning Rep. ¶ 190; *id.* at Attachment D-1.

C. Pre-judgment Interest

"In Delaware, pre-judgment interest is awarded as a matter of right."[690] "Prejudgment interest serves two purposes: first, it compensates the plaintiff for the loss of the use of [its] money; and second, it forces the defendant to relinquish any benefit that it has received by retaining the plaintiff's money in the interim."[691]

1. Contract Damages

The Merger Agreement states that, for any earnout payment not paid within 10 days of J&J delivering notice of a milestone's achievement:

> interest shall accrue on such unpaid amount at a rate per annum equal to the prime rate of interest reported from time to time in *The Wall Street Journal*, calculated on the basis of the actual number of days elapsed over three hundred sixty (360), from the date such amount should have been paid pursuant to the terms of this Agreement . . . to the date of actual payment in full of such amount.[692]

The Merger Agreement also states that J&J will "notify the Stockholders' Representative in writing within fifteen (15) days after the achievement" of any regulatory milestone.[693] J&J "shall, or shall cause the Surviving Corporation or the Paying Agent to, pay the applicable Earnout Payment . . . within ten (10) days after such notice is delivered."[694]

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[690] *Citadel Hldg. Corp. v. Roven*, 603 A.2d 818, 826 (Del. 1992).

[691] *Brandywine Smyrna, Inc. v. Millennium Builders, LLC*, 34 A.3d 482, 486 (Del. 2011).

[692] Merger Agreement § 2.07(d)(vii).

[693] *Id.* § 2.07(c).

[694] *Id.* § 2.07(c).

Guided by these provisions, Manning calculated pre-judgment interest on Fortis's breach of contract damages using per-quarter averages of daily prime rates as reported in The Wall Street Journal, adjusted to reflect one quarter of a 360-day year.[695] He conservatively assumed that the milestone payments would have been received 25 business days after the last day of the milestone period.[696] He calculated pre-judgment interest through May 18, 2023 (the date through which he was asked to calculate damages), applying a floating interest rate that compounds quarterly.[697]

I adopt Manning's approach as both fair and consistent with the Merger Agreement. The prime rate was not only agreed upon by the parties, but also considered the best measure of the commercial lending rate used by banks for loans to creditworthy customers.[698] Using a variable rate accounts for the economic realities during the relevant period, which saw significant swings in interest rates.[699] Whether to award compound or simple interest is a discretionary matter for this

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[695] Manning Rep. ¶ 87.

[696] *Id.*

[697] *Id.*

[698] *Id.* ¶ 87 n. 202 (citing Federal Reserve Website, *FAQs*, "What is the Prime Rate, and Does the Federal Reserve Set the Prime Rate?" https://www.federalreserve.gov/faqs/credit_12846.htm).

[699] *See Gentile v. Rossette*, 2010 WL 3582453, at *2 (Del. Ch. Sept. 10, 2010) ("In departing from a legal rate of interest fixed at the time of the wrongdoing, our courts have considered concepts such as 'the realities of the relationship' between the parties, whether a particular party was the primary cause for a delay in the litigation, as well as general 'fundamental economic realit[ies].'" (citation omitted)).

court.[700] J&J's sophistication, plus the years that it benefitted from non-payment of the earnout, support compound rather than simple interest.[701]

The only applicable milestones that expired before May 18, 2023 are the General Surgery Milestone and the Soft Tissue Ablation Milestone. A further interest calculation from May 19, 2023 through the date of judgment will be needed for these milestones, as well as the four iPlatform umbrella milestones for which Fortis proved its entitlement to damages.

For the General Surgery Milestone, Manning computed pre-judgment interest from (1) the milestone end date plus 25 business days through (2) May 18, 2023. For the first quarter of this period, for each milestone, he multiplied the damages by the quarterly average prime rate and by the number of days in the quarter divided by 360 to determine interest. For each of the remaining quarters, for each milestone, he multiplied the sum of the expected payment and cumulative interest by the number of days in the quarter divided by 360 and by the quarter's average prime rate.[702] The resulting calculation is:[703]

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[700] *NGL Energy P'rs LP v. LCT Cap., LLC*, --- A.3d ---, 2024 WL 2716005, at *4 (Del. May 28, 2024).

[701] *See Valeant Pharms. Int'l v. Jerney*, 2007 WL 2813789, at *8 (Del. Ch. Mar, 1, 2007).

[702] Manning Rep. ¶ 93.

[703] *Id.* at Attachment B-20 (calculating interest for the General Surgery Milestone by quarter beginning in Q1 2022 based upon the average prime rate assuming a cumulative payment of $300,000,000).

Quarter	Cumulative Payment	Days	Years	Average Prime Rate	Interest in Quarter	Cumulative Interest
2022 – Q1	$300,000,000	56	0.16	3.29%	$1,537,366	$1,537,366
2022 – Q2	$300,000,000	91	0.25	3.93%	$2,994,434	$4,531,799
2022 – Q3	$300,000,000	92	0.26	5.37%	$4,181,586	$8,713,385
2022 – Q4	$300,000,000	92	0.26	6.82%	$5,380,273	$14,093,658
2023 – Q1	$300,000,000	90	0.25	7.69%	$6,041,237	$20,134,895
2023 – Q2	$300,000,000	47	0.13	8.06%	$3,370,596	$23,505,491
Total	n/a	n/a	n/a	n/a	$23,505,491	**$23,505,491**

2. Fraud Damages

In assessing pre-judgment interest for Fortis's fraud damages, Manning considered the period from April 1, 2019 (the merger date) through May 18, 2023.[704] "The Court of Chancery generally looks to the legal rate of interest, as set forth in 6 *Del. C.* § 2301, as the 'benchmark' for the appropriate rate of pre-[judgment] interest."[705] Manning followed this approach and applied a floating rate that compounds four times a year. As with his interest calculation for Fortis's contract damages,[706] this is reasonable.

Manning determined the average Federal Reserve discount rate for each quarter during the relevant period and added 5% to these averages, consistent with the statutory rate. He calculated interest by multiplying the difference in the eNPV

[704] *Id.* ¶ 186.

[705] *Murphy Marine Servs. of Del., Inc. v. GT USA Wilm., LLC*, 2022 WL 4296495, at *24 (Del. Ch. Sept. 19, 2022) (citation omitted).

[706] *See supra* note 700 and accompanying text.

and the actual value by the quarterly interest rate and the days in each quarter divided by 365, while compounding on a quarterly basis.

The resulting calculation is:[707]

Quarter	Cumulative Payment	Days	Years	Interest Rate[708]	Interest In Quarter	Cumulative Interest
2019 – Q2	$60,865,748	91	0.25	8.00%	$1,213,980	$1,213,980
2019 – Q3	$60,865,748	92	0.25	7.81%	$1,221,571	$2,435,551
2019 – Q4	$60,865,748	92	0.25	7.33%	$1,170,062	$3,605,614
2020 – Q1	$60,865,748	91	0.25	6.82%	$1,096,101	$4,701,715
2020 – Q2	$60,865,748	91	0.25	5.25%	$858,215	$5,559,930
2020 – Q3	$60,865,748	92	0.25	5.25%	$879,003	$6,438,933
2020 – Q4	$60,865,748	92	0.25	5.25%	$890,635	$7,329,568
2021 – Q1	$60,865,748	90	0.25	5.25%	$882,802	$8,212,370
2021 – Q2	$60,865,748	91	0.25	5.25%	$904,166	$9,116,536
2021 – Q3	$60,865,748	92	0.25	5.25%	$926,067	$10,042,603
2021 – Q4	$60,865,748	92	0.25	5.25%	$938,321	$10,980,925
2022 – Q1	$60,865,748	90	0.25	5.29%	$937,682	$11,918,607
2022 – Q2	$60,865,748	91	0.25	5.94%	$1,078,305	$12,996,912
2022 – Q3	$60,865,748	92	0.25	7.36%	$1,370,920	$14,367,832
2022 – Q4	$60,865,748	92	0.25	8.83%	$1,673,848	$16,041,680
2023 – Q1	$60,865,748	90	0.25	9.69%	$1,837,269	$17,878,949
2023 – Q2	$60,865,748	47	0.13	10.07%	$1,021,102	$18,900,052
Total	n/a	n/a	n/a	n/a	$18,900,052	**$18,900,052**

D. Attorneys' Fees

In addition to damages, Fortis invokes Section 8.02 of the Merger Agreement to request the reimbursement of its attorneys' fees from this lawsuit. Section 8.02

[707] Manning Rep. at Attachment D-6 (calculating interest for the Soft Tissue Ablation Milestone by quarter beginning in Q2 2019 based upon the legal rate of interest assuming a cumulative payment of $60,865,748).

[708] This column reflects the Federal Reserve discount rate plus 5%. *See* 6 *Del. C.* § 2301(a).

states that J&J will indemnify Auris for "any and all Losses suffered or incurred by any such Seller Indemnified Party arising from or relating to . . . any breach of or failure to perform any covenant, agreement or obligation . . . contained in this Agreement."[709] "Losses" are defined as:

> any and all debts, obligations, losses, liabilities, damages, [t]axes, costs of investigation and other third party costs and expenses, in each case, whether known or unknown, absolute or contingent, liquidated or unliquidated, direct or indirect, due or to become due, accrued or not accrued, asserted or unasserted, related or not related to a Third Party Claim or otherwise (in each case excluding (x) incidental consequential and lost profits (in each case to the extent not reasonably foreseeable) and (y) punitive damages or damages based upon a financial metric multiple (except, in each case, to the extent awarded in a final non-appealable judgment and actually paid to a third party as part of a Third Party Claim)).[710]

There is no language in this provision, or elsewhere in the Merger Agreement, contemplating an award of attorneys' fees for litigation. Granting Fortis's request would force me to "interpret the provision in an expansive way that would be inconsistent with the American Rule," which requires each party to bear its own attorneys' fees.[711] I decline Fortis's invitation to do so.

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[709] Merger Agreement § 8.02(ii).

[710] *Id.* § 8.01.

[711] *Senior Housing Cap., LLC v. SHP Senior Housing Fund, LLC*, 2013 WL 1955012, at *45 (Del. Ch. May 13, 2012).

E. Total Damages

Fortis has proven its entitlement to contract damages in connection with five iPlatform regulatory milestones. It has also proven its entitlement to fraud damages in connection with the Soft Tissue Ablation Milestone. Pre-judgment interest, as set forth above, will be applied to these figures. Interest through May 18, 2023 is included in the total below for applicable milestones, though interest will also be awarded from that date through the date of judgment for the rest. In addition, Fortis will be entitled to post-judgment interest.

Fortis's total damages, based upon the available interest calculations, are:

Milestone	Damages	Interest[712]	Total
Breach of Contract			
General Surgery Milestone	$300,000,000	$23,505,491	$323,505,491
Upper Abdominal Milestone	$120,000,000		$120,000,000
Lower Abdominal Milestone	$120,000,000		$120,000,000
Urologic Milestone	$120,000,000		$120,000,000
Gynecologic Milestone	$120,000,000		$120,000,000
GI Milestone	$120,000,000		$120,000,000
Fraud			
Soft Tissue Ablation Milestone	$60,865,748	$18,900,052	$79,765,799
Total Damages			
	$960,865,748	$42,405,543	**$1,011,271,291**

IV. CONCLUSION

J&J breached Section 2.07(e) of the Merger Agreement and the implied covenant of good faith of fair dealing. These breaches led iPlatform to miss the

[712] This column does not include pre-judgment interest from May 19, 2023 through the date of judgment or post-judgment interest.

General Surgery, Upper Abdominal, Lower Abdominal, Urologic, Gynecologic, and GI Milestones. J&J also committed fraud relating to the Soft Tissue Ablation Milestone. Fortis is entitled to damages, plus pre- and post-judgment interest, as outlined above.

Within 14 days, Fortis is asked to file an updated interest calculation consistent with the methodology adopted above. The parties are asked to confer on and file a proposed final order within 10 days of Fortis's interest submission.